DNV·GL

SERVICE SPECIFICATION

DNVGL-DS-HC403

Managing Infection Risk Centre of Excellence Certification Program

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1 BACKGROUND

The Managing Infection Risk (MIR) Standard was developed by DNV GL to provide a modern, comprehensive, risk-based and practical framework to help organizations improve their management of infection risk. It adopts a structure based upon 18 elements that address all areas associated with the design, operation and management of healthcare facilities. The standard is compatible with World Health Organization (WHO), US Centres for Disease Control (CDC) and other national / international guidelines, providing a compatible management framework for these often relatively technical documents, together with allowing for better integration and ease of implementation.

2 WHY WE NEED THE MIR PROGRAMME

Healthcare organizations today are faced with an ever increasing demand to improve the quality of patient care and to provide a safe and cost-effective operation that contributes to sustainable business development and growth. Lower risk tolerance, more intense scrutiny by stakeholders, together with the need to stay ahead of the game, means many healthcare organizations increasingly need to demonstrate their ability to provide safe, high quality and cost effective services. One vital aspect of this is to ensure careful management of infection risks through reducing healthcare-associated infections and by being well prepared for the threat of pandemics. In order to achieve this, organizations need to adopt structured and robust approaches to manage these challenges, as they seek to measure and improve their performance in infection risk management.

3 HOW THE MIR PROGRAMME WORKS

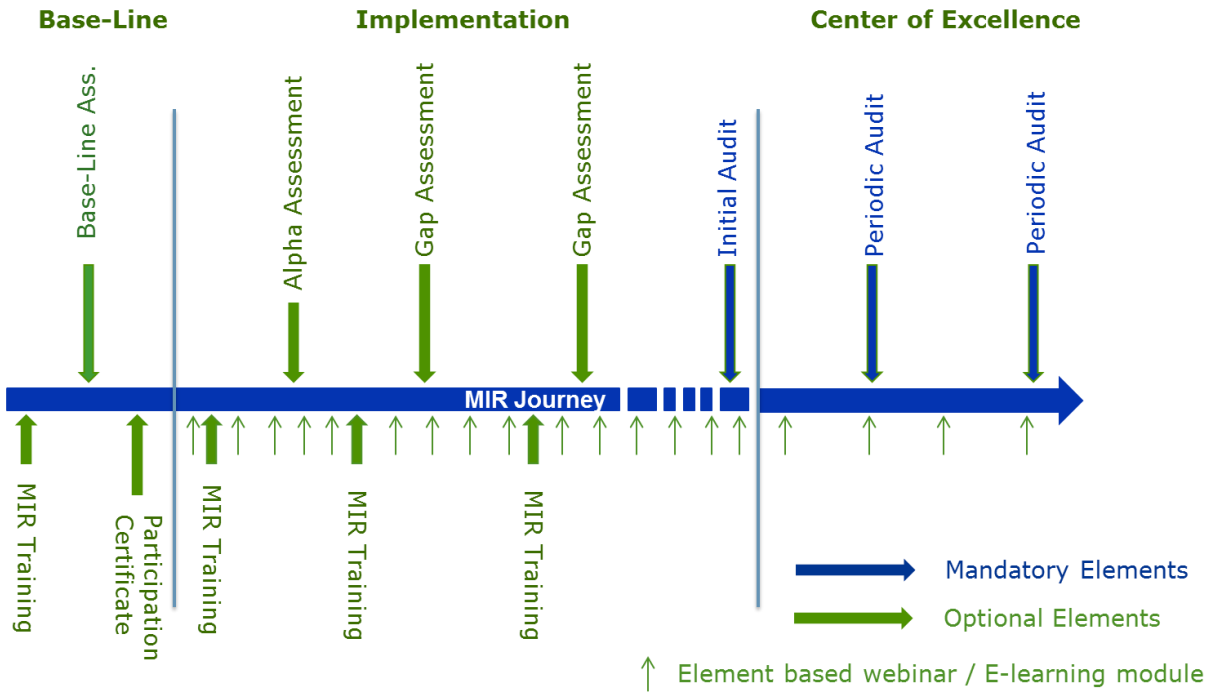
The MIR Standard and Programme is a journey that supports healthcare organizations to focus on the critical areas, drive continual improvement and improve performance through the adoption of recognised good practice in infection risk management. For many organisations the MIR

Programme will be a significant undertaking with a need to embrace real and meaningful organizational change.

The programme is assessment-orientated being supported by a range of optional training and gap assessment offerings, leading to the award of a DNV GL Managing Infection Risk Centre of Excellence (MIR CoE). Once awarded the designation as a MIR CoE requires successful periodic audits and recertification every third year. The training can be in the form of formal classroom training and / or webinars, designed around a series of courses describing the MIR Standard, together with additional 'drill downs' on specific subject areas or element-specific modules.

4 THE MIR JOURNEY

The MIR journey, as a potential pathway for those organizations committed to achieving MIR CoE status is depicted below. As part of the initial planning phase, organisations will be asked to complete an MIR Information sheet that provides DNV GL with key information regarding the type of hospital and the services and activities relevant to infection control that they perform. This information will provide the foundation from which a programme can be tailored to suit the needs of the healthcare organization as well as the number of auditor days that DNV GL will require for the certification audits.



4.1 Establishing the Base-line

The first formal stage in the MIR journey for an organisation will often be to undergo a Base-Line Assessment. The Base-Line Assessment will entail interviews with key individuals, review of documents and site visits of patient care and support areas. The Base-Line Assessment results in an audit report highlighting the strengths and weaknesses of the organisations MIR system and identifies areas where it is not compliant with the MIR Standard. The Base-Line Assessment is also designed to raise awareness and understanding of the approach amongst a cross-section of staff that are involved in infection risk management and who will be important in driving change on the road to becoming a MIR CoE. Using the findings in the Base-Line Assessment report, the healthcare organization prepares a Corrective Action Plan (CAP) that outlines how they will address any deficiencies identified and move towards being a MIR CoE . Once the CAP has been reviewed and approved for completeness and by DNVGL then the organisation receives a “MIR Letter of Participation” as a public acknowledgment that the organisation has committed to work towards compliance with the MIR Standard.

Some healthcare organizations may also choose to have specific training, undergo an Alpha Assessment (see below) or a specific, targeted GAP assessment prior to requesting the Base-Line Assessment. It is also possible for organisations to skip the baseline step and move directly to the implementation phase or even the formal certification phase (in which case they will not be entitled to receive a “letter of MIR Participation”).

4.2 MIR Implementation

Organisations wishing to move forward and implement MIR can be supported by a range of DNV GL training options as well as a range of assessments targeted towards specific MIR elements or organisational departments or functions. Training is optional, but is strongly recommended to all participating organizations.

4.2.1 GAP Assessments

Targeted Gap Assessments will also be offered as a means of checking progress against the CAP and preparing for the MIR CoE assessment. Gap Assessments will typically be carried out by two DNV GL auditors over a two day period, but this can be agreed upon with the healthcare organization on a case-by-case basis.

4.2.2 Alpha Assessments

The Alpha Assessment is a high level assessment based on the perception of the healthcare organization’s employees regarding their organisations MIR performance and compliance. It is not a detailed audit, and detailed checking of evidence is not required. The auditor interviews a cross

section of the organization's employees, including senior managers, infection control staff, medical and nursing staff, other care workers, facilities staff and patients. Alpha Assessments can also be used as an additional step to engage the hospital prior to establishing the base-line.

4.2.3 Initial (Certification) Audit

Once a hospital is confident that they meet the MIR requirements they can request a full initial audit in order to qualify for MIR CoE status. The audit days required for the initial audit are calculated based upon the size, complexity and infection risks of the healthcare organization. Upon a successful audit the organisation will be designated a 'DNV GL Managing Infection Risk Centre of Excellence', a certificate will be issued reflecting this and this will be valid for three years.

5 CENTER OF EXCELLENCE

The 'DNV GL Managing Infection Risk Centre of Excellence' designation and associated certificate is maintained over a three year period and consists of two annual periodic audits followed by a recertification audit. The recertification audit assesses compliance against all 18 MIR elements while the periodic audits will be more limited and cover roughly half of the elements (i.e. so all elements are covered at least once during the periodic audits). In addition both the periodic and the recertification audits use a risk based approach whereby the team lead and the organisation work together to identify specific focus areas for the audit based on the infection prevention goals and risks faced by the organisation.

Both the periodic and recertification audits are scheduled around the time of year of initial certification with the recertification audit taking place at least 30 days prior to the MIR CoE status elapsing.

6 WHAT TO EXPECT FROM THE MIR AUDIT PROCESS

At least 10 days prior to the planned audit the healthcare organization will receive from the team leader:

- An audit plan
- List of documents required to be reviewed onsite
- Request for access to patients records (in countries where this is applicable)

6.1 The Opening Meeting

The Audit Team Leader will open the meeting, document attendance and address the following areas:

- An introduction of audit team members, including any additional auditors who may join the team at a later time, the general area that each will be responsible for, and the types of documents that they may request
- A review of the purpose, scope of the audit, and audit plan (the agenda may be adjusted as necessary)
- Brief explanation of the audit process
- Clarification of all organization areas and locations, departments, and patient care settings under the scope statement that will be audited
- A review of how patient confidentiality shall be handled
- Discuss the location (e.g. conference room) where the team may meet privately during the audit
- Determine how the facility will ensure that auditors are able to obtain the photocopies of material, records, and other information as they are needed
- Obtain the names, locations, and telephone numbers of key staff to whom questions should be addressed
- Agree on communication lines for the audit

6.2 Audit Structure

The audit will typically consist of element-specific interviews in combination with site visits to areas of patient care (e.g. wards, patient rooms, operating theatres, etc.), support areas (e.g. kitchens, laundry, etc.) and engineering areas (e.g. HVAC areas, water purification, emergency power supply areas). The audit Team Leader will prioritize the areas to be visited based on the perceived infection risk and on the interview findings and other direct observations.

The audit team will be accompanied by assigned healthcare organization staff throughout the audit. The team will meet at least daily (typically each morning / late afternoon) with the healthcare organization's leadership to assess the status of the audit, progress of completion of assigned activities, areas of concern, and to identify areas for additional investigations. The meetings will include an update by each auditor, addressing findings and areas of concern that have been identified. If areas of concern are identified in the discussion, the audit team and the healthcare organization staff will coordinate efforts to obtain additional information, if appropriate. The healthcare organization staff will have the opportunity to present additional information or to offer explanations concerning identified issues.

6.3 Documents Handling

The Audit Team Leader shall keep a register of documents provided by the healthcare organization to control that all documents are received and returned. If it is desirable to take documents off-site during the audit, the Audit Team Leader will first seek permission from the healthcare organization. All documents shall be returned to the organization at the end of the audit unless written permission is given by the healthcare organization for the audit team to retain specific documents for their report-writing purposes. Documents with patient identifiable information shall NOT be removed from site. In the event that a medical record (or any other document that contains patient identifying information) is reviewed and referenced, the auditor will maintain a legend, so that any patient protected health information remaining with DNV GL is de-identified. This typically involves removing names, postal addresses, medical record number, telephone numbers and email addresses.

6.4 Documents Required By The Auditors

To facilitate the on-site audit process, the healthcare organization will be required to make a number of documents available to the DNV GL auditors.

The following key documents should be sent prior to the audit if they are available electronically and do not contain any patient identifiable information (if this is not the case then they should be available at the start of the audit (one copy per auditor),:

- Organizational chart;
- Quality and/or safety manual or plan
- Infection control plan
- Minutes of the infection prevention and control committee for the last 6 months
- Infection risk management policies and procedures

Additional documents that might be requested by the audit team and that should be available at short notice include the following:

- Map / floor plan, including support areas and locations for patient care and treatment areas
- List of MIR IT-related information (i.e. manuals, web-based training, patient records, etc.)
- Data on infection rates, outbreaks and performance in accordance with local, national targets and other performance indicators
- Accident / incident reports relevant to infection prevention and control
- Minutes of relevant committee meetings:

  - Medical Executive;
  - Safety;
  - Quality oversight
- Audit plans and reports
- Minutes of the Quality Oversight / Management Review Committee
- Minutes from Environment of Care / Safety Committee
- List of contracted services, companies and individuals
- Relevant risk assessments (i.e. infection control, general facility assessments, etc.)
- Emergency plans and records of exercises
- Security plans
- Equipment lists / asset registers
- Equipment certification records
- Lists of MIR-relevant key contractors
  - Clinical services
  - Cleaning
  - Security
  - Laundry
  - Catering
  - Etc.
- Building commissioning plans
- Relevant policies, procedures and instructions
  - Risk assessment and management
  - Training and competency
  - Cleaning, disinfection, decontamination and sterilization
  - Microbial surveillance
  - Antibiotic use
  - Accident / incident investigation

6.5 Audit Interviews

The purpose of the audit is to develop an independent assessment of the effectiveness of the organisations infection risk management system: how well does it protect patients, visitors and staff from infection risks. This will include describing strengths and any identified weaknesses of the system as well as identifying risks that management should be aware of.

Information will be collected through a combination of document review, interviews with staff and site tours to areas of the organisation providing direct care as well as to support and engineering areas. Interviews will include formal element-specific interviews with key staff, as well as some informal interviews of frontline and support staff, contractors and possibly visitors and patients (after consent has been given through hospital staff). When conducting interviews, the auditors will maintain documentation of each interview conducted.

The audit team will make every effort to ensure any findings are raised with the organisation as soon as is practical and efforts will be made to have findings verified by facility personnel. For example, if a member of the surgical staff is observed wearing inappropriate clothing and/or PPE then this will be taken up immediately with staff accompanying the audit team so that the context can be clarified and verified, and if appropriate, the surgical staff can be approached. In cases where such verification has not been possible, the Lead Auditor will take this into consideration when reporting findings and may initiate appropriate follow-up actions as required (e.g. requests for further information and / or inclusion of issue as focus area for subsequent audits).

6.6 Audit Findings

During the audit, the audit team will have regular team meetings to integrate findings, review and analyse all information collected from auditor observations, interviews, and record reviews, and to determine whether or not the organization meets the appropriate MIR Standard requirements. Any deficient practice (referred to as a 'non-conformity') will be discussed and flagged for further investigation during the on-site audit. The team will ensure that their findings are supported by adequate documentation of auditor observations, interviews and document reviews. Findings will be categorised according to the following criteria:

6.6.1 Noteworthy Efforts

The audit team will provide an independent and impartial assessment of the MIR system and an important part of this exercise is to identify and highlight areas where positive recognition is deserved. Examples of these noteworthy efforts include:

- Performance exceeds expectations in terms of efficiency and/or effectiveness and could be a model for best practice
- Areas that demonstrate significant improvement
- High levels of commitment and/or motivation

Noteworthy efforts shall be reported at the closing meeting and potentially in the Management Summary Report, but not entered into the List of Findings.

6.6.2 Non-Conformance Category 1 (major)

A non-conformity is raised when there is objective evidence that a requirement has not been addressed (intent), a practice differs from the defined system (implementation), or the system is not effective (effectiveness).

A non-conformance will be categorised as 'Major' when there is either:

- The absence of one or more required system elements or a situation which raises significant doubt that products or services will meet the MIR requirements.
- A group of category 2 non-conformities indicating inadequate implementation or effectiveness of the system relevant to an element of the standard.
- A category 2 non-conformity that is persistent (or not corrected as agreed by the organization) shall be up-graded to category 1.
- A situation that on the basis of available objective evidence may directly lead to unacceptable infection risk to patients, staff or visitors.

6.6.3 Non-Conformance Category 2 (minor)

A non-conformance will be categorised as 'Major' when there is a lapse of either discipline or control during the implementation of system/procedural requirements, which does not indicate a system breakdown or raise doubt that products or services will meet requirements. Overall system requirement is defined, implemented and effective.

6.6.4 Observations

An observation is not a non-conformance, but something that could lead to a non-conformance, if allowed to continue uncorrected; or an existing condition without adequate supporting evidence to verify that it constitutes a non-conformance.

6.6.5 Opportunities for improvement

An opportunity for improvement relates to areas and / or processes of the healthcare organization which may meet the minimum requirements for the MIR Standards but which could be improved. An opportunity for improvement may be a system or performance related issue, and is normally

assessed by drawing upon the experience of the audit team and their knowledge of international best practice.

6.7 The Closing Meeting

The Audit Team Leader chairs the closing meeting where the team will present their findings, and disclose any deficiencies they noted during the audit. If the audit team has determined there are some non-conformities, they will present these at the closing meeting. The Audit Team Leader shall ensure that all findings (to be included in the Audit Report) are presented at the closing meeting, and that the healthcare organization is given an opportunity to review and discuss these. If the closing meeting was audio or video taped, the Audit Team Leader shall be provided with a copy of the tape in its entirety before leaving the healthcare organization.

The Healthcare Organisation is responsible for deciding who attends the close-out meeting but this commonly involves available key staff that have been involved in the audit and would normally involve relevant top management.

6.8 After The Audit

The reporting format for GAP and Alpha assessments will depend on the needs of the organisation being assessed. For all other audits the Audit Team Leader will gather input from the audit team and collate a preliminary Management Summary report. and associated List of Findings. Following an independent technical review a pdf of the Management summary and list of findings in excel format will be sent to the organisation. The report should be received by the hospital within 15 working days of the completion of the audit.

7 FOLLOW-UP

No formal follow-up by DNV GL is required for GAP assessments or Alpha assessments. Healthcare organizations are not required to develop, update or submit Corrective Action Plans, although they may wish to develop one for internal purposes, to facilitate improvement strategies. For other audits the follow-up is as follows.

7.1 Base-Line Assessment

Healthcare organizations will be required to develop a Corrective Action Plans (CAP) and submit this to the Audit Team Leader within 30 working days of receiving the Management Summary report and List of Findings (LoF) for the Base-Line Assessment.

The LoF is provided as an excel file and space is provided for the organisation to indicate the following:

1. Immediate Correction: Immediate action taken to eliminate the non-conformity

2. Analysis of causes: An analysis of possible causes to non-conformities as well as identification of other areas, sites and/or processes that have the potential to be affected by the same NC.

3. Implementing proposed corrective actions: Dominant causes identified in analysis are linked to proposed corrective actions whereby process or system changes will be made to ensure that the NC does not recur. Timeframes should be indicated as well as the person responsible for implementing the corrective action measure(s) and the performance measure(s) and/or other supporting evidence that will be monitored to ensure the effectiveness of the corrective action(s) taken.

The Audit Team Leader will review the Corrective Action Plan and will either inform the healthcare organization that it has been approved, or shall request additional actions or information. Once the CAP has been approved the hospital shall be issued with a MIR Letter of Participation, valid for a period of one year, and they will be identified as a MIR Participant on the DNV GL website. To extend the validity of the Letter of Participation the organisation needs to demonstrate progress against their action plan through additional GAP assessments (minimum 1 auditor day) or by providing evidence for review by the team leader off-site.

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7.2 Initial, Periodic and Recertification Audit Follow-up

Following the audit the healthcare organisation is required to complete the same three steps that are outlined in 7.1. The healthcare organisation shall submit the List of Findings within due time and with pertinent parts filled in together with required supporting documentation as evidence. The organisation is also encouraged to give their response to any observations that might have been raised, however this is not a formal requirement.

The subsequent close-out activities will depend on the type of non-conformity:

7.2.1 Major (Category 1):

Within the maximum of 90 days the organisation shall be able to provide evidence of effectively implemented corrections and corrective actions. DNV GLs follow-up shall normally be performed on-site in order to perform proper verification of effective implementation and to close the NC. In exceptional cases, and with justification, follow-up may be performed off-site as a desk review.

This may be applicable where the team leader considers that solely documentary evidences are sufficient to close the NC.

7.2.2 Minor (Category 2):

Within the maximum of 90 days the organisation shall be able to provide evidence of effectively implemented corrections and corrective actions. DNVs follow-up shall normally be performed off-site, based on received documentation. However, based on the judgment of the team leader, an on-site follow-up may be decided also for category 2 NCs. This may e.g. be applicable in case of many NCs and in cases where only documentary evidences are considered insufficient.

For re-certifications the follow-up of NCs and recommendation for certification shall be performed no later than 10 working days before expiry date of the certificate in order that the validity date of the certificate is maintained.

8 ISSUE OF MIR CENTER OF EXCELLENCE CERTIFICATE

Once the Team Leader is satisfied that all major non-conformities have been closed and that all minor non-conformities have been satisfactorily addressed (i.e. an adequate CAP has been provided indicating that the healthcare organisation will complete actions to close the non-conformity within the 90 days) then he/she can recommend certification. Once the independent review of the process and documents has been completed a Certificate will be issued that is valid for three years and the organisation will be identified as a CoE on the DNV GL web-site. Organisations will also be provided with a MIR CoE Certification Mark that can be used to promote their achievements (rules for the use of the MIR CoE Certification Mark are included in the Certification agreement)

9 INITIATION OF SUSPENSION OR WITHDRAWAL

Suspension is the time-limited invalidation of a certificate while withdrawal is the permanent invalidation of a MIR CoE certificate.

DNV GL - Business Assurance may initiate suspension, for example in cases where the:

1. The MIR management systems have persistently and seriously failed to meet certification requirements, e.g.:

- Failure to respond adequately to identify identified non-conformance(s)
- Management system does not reflect the current organisation and processes, e.g. as a result of changes, acquisitions, diversification etc.

- Major part of the management system not implemented

2. Surveillance audits and recertification audits not allowed to be conducted according to required frequency or as scheduled

3. Violation of the terms of the signed certification agreement, e.g.:

- •Non-payment of fees
- •Incorrect use of the MIR certification mark and reference to certification

4. Customer voluntarily requesting temporary suspension

5. Evidence received from authorities etc. that could affect the status of certificate, e.g.:

- Evidence of non-compliance to regulatory/statutory requirements relevant for the MIR management system
- Evidence of a non-effective MIR management system in case of serious incidents/accidents.

The management and authorized personnel within the DNV GL - Business Assurance unit who issued the MIR CoE certificate shall decide on the action to be taken, based on a review and duly considerations of evidences. Suspension of a MIR CoE certificate is normally initiated as the first step, followed by withdrawal if the issue of concern is not resolved within due time. Dependent on the seriousness of the case, DNV GL - Business Assurance may decide a direct withdrawal of the MIR CoE certificate.

Where failure of the management system is related to a specific part of the organisation, specific products etc, DNV GL - Business Assurance may also consider a reduction in the scope of certification as an alternative to suspension. DNV GL - Business Assurance may also choose to only give the customer a warning that suspension is being considered.

9.1.1 Suspension

The decision to suspend a certificate shall be communicated to the customer by a formal letter. The letter shall include:

- A statement on the decision to suspend the MIR CoE certificate including a proper description of the situation, argumentation and reference to objective evidences.

- The right to respond and appeal to the decision. Normally a 10 working days notice for response and appeal are given. An appeal may be lodged through the complaints procedure.
- Start date of the suspension (normally from the date the letter was received).
- Conditions and due date of required action in order to revoke the suspension, and the consequence if satisfactory actions are not performed.
- The means of follow-up by DNV GL - Business Assurance to verify that conditions have been met and needed corrective actions have been implemented
- A statement that the MIR CoE certificate is invalid during suspension and that use of all advertising matter containing a reference to certification are prohibited during time of suspension
- A statement that both the customer and DNV GL - Business Assurance shall inform all enquirers that the MIR CoE certificate is suspended
- A MIR CoE certificate shall not be suspended for more than 6 months.

9.1.2 Follow up

DNV GL - Business Assurance will verify that conditions are met and requested corrective actions are implemented. Dependent on this verification, DNV GL - Business Assurance will either:

- Declare a positive result, revoke the suspension and declare a valid certificate
- Declare a negative result due to failure to resolve the issues that resulted in suspension. This situation will normally result in permanent withdrawal of the certificate. (See below)

In either case the customer will receive a letter confirming the result.

9.1.3 Withdrawal

Withdrawal of the certificate shall be initiated if:

- The customer does not meet the conditions of suspension
- A suspension is not considered to be an adequate action.

The decision to withdraw a certificate shall be formally communicated to the customer including the requirements to:

- Terminate use of the certification mark and any reference to certification
- Return certificate(s) and copies to DNV GL - Business Assurance

The customer has a right to appeal. An appeal may be lodged through the complaints procedure.

10 COMPLAINTS AND APPEALS

A complaint is any objection to how we deliver our services and content of the services, how we organise and administer our work. This includes appeals on decisions made by DNV GL - Business Assurance, e.g. withdrawal of certificates, response to previous complaints. The process is valid for any complaint raised by a customer, potential customer or any stakeholder at large who have objection to our services, our decision in a certification process or way of operation.

A description of the complaints procedure and a contact form for submitting complaints can be found on our here: http://www.dnvba.com/Global/contact-us/Pages/complaints-procedure.aspx