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Application of EN14181 and EN15267 to Electronic Noses: Challenge or Provocation?

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Technical Standards EN 14181 and EN 15267 describe the quality programs that must be followed in the realisation, validation and management of an AMSs (Automatic Measurement Systems), continuous sampling and measuring systems for emission and ambient air pollutants control.
Their scope is to guarantee the final user and Local Authorities of the main characteristics given by every AMS, let the user establish a proper maintenance procedure and give information on real uncertainties of instrument measurements.
Implementation of electronic noses for emission and ambient air purposes, since now out of the scopes given by the cited standards, arises the question of a possible integration of e-noses in the AMSs universe, in particular in order to give answers on real uncertainties that such instruments can provide.
The paper wants to illustrate the main characteristics of EN 14181 and EN 15267 standards and analyse possible implementation of e-noses to them, with particular focus on qualification and the maintenance that should be applied to e-noses, and on the uncertainties aspects.

1. Introduction

E-Noses are becoming more and more available for the industrial market in order to be used not only as scientific or support instruments (Guillot, 2016;Milan et al, 2012), but as 'official' emission and air quality monitors. As an example, consider the work of CEN TC 264 WG 41 (Electronic Sensors for Odorant Monitoring), that certifies the attention that Legislators, Plant Owners and Instrument Producers give to such argument.
Starting from 2000, CEN experts made a great effort to define all the aspects of the so called 'Automatic Measuring System' (AMS), the automatic analysers allowed for continuous monitoring, either for emissions and ambient air use.
In particular the two documents that define the basic structure of AMSs are the standards EN 14181:2014 (first edition was released in 2005) and the EN 15267 series.
EN14181:2014 specifies the procedures for establishing Quality Assurance Levels (QALs) for automated measuring systems (AMS) installed on industrial plants for the determination of the flue gas components and other parameters. It specifies:
- A procedure (QAL2) to calibrate the AMS and determine the variability of the measured values obtained by it, so as to demonstrate the suitability of the AMS for its application, following its installation;
- A procedure (QAL3) to maintain and demonstrate the required quality of the measurement results during the normal operation of an AMS, by checking that zero, span and other relevant characteristics are consistent with those determined during QAL1;
- A procedure for the annual surveillance tests (ASTs) of the AMS in order to evaluate (i) that it functions correctly and its performance remains valid and (ii) that its calibration function and variability remain as previously determined.
QAL1 is the evaluation of expected performances of an AMS, done before its installation and using the data from the certification, necessary to evaluate the 'fit for purpose' of the AMS.

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EN 15267-1/2/3:2009 specifies the general principles, including common procedures and requirements, for the product certification of AMSs for *monitoring ambient air quality* and *emissions* from stationary sources. This product certification consists of the following sequential stages:
a) Performance testing of an automated measuring system;
b) Initial assessment of the AMS manufacturer's quality management system;
c) Certification;
d) Surveillance.
This European Standard applies to the certification of *all AMS for monitoring ambient air quality and emissions* from stationary sources for which performance criteria and test procedures are available as European Standard.
Possible implementation of e-noses to AMSs level imposes that such units are to be investigated under the quality requirements of these standards.

2. E-Noses models

Many different designs of an e-nose are possible. In this work two major solutions are investigated: an independent version (Figure 1) and an internet based solution (Figure 2).

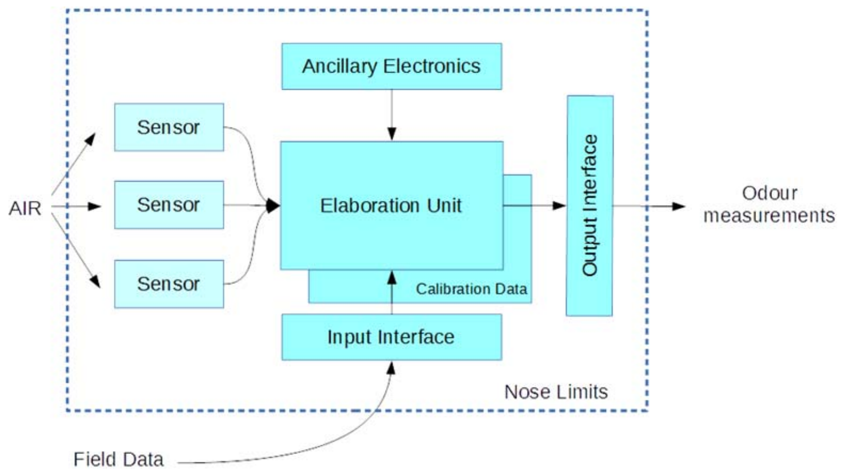

Figure 1: Basic scheme of an independent e-nose

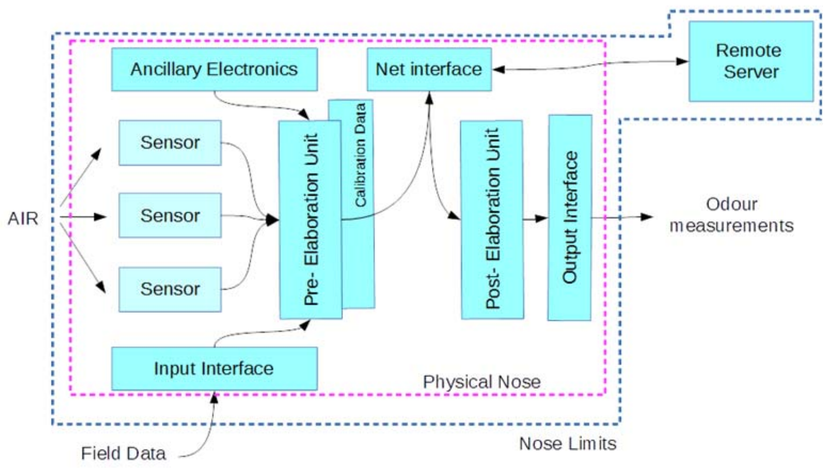

Figure 2: Basic scheme of a web based e-nose

In both solutions, a general array of physical sensors generates a finite numbers of signals from the ambient air of the emissions analysis. These signals are sent to an elaboration unit, together with a certain number of signals acquired from the field (e.g. temperatures, flow rates, pressures, etc.).
Both solutions, also, are based on the use of a data base in order to store the information necessary to evaluate results, like, e.g. calibrations, QA checks, set up data, historic and training data.
The main difference between the two solutions is that, while in the first one, the elaboration unit is able to analyse all the inputs and produce on its own the required output, in the second, data are only pre-elaborated and sent to an external server where the final results are evaluated and sent back to the analyser for the final output.
Such descriptions are intentionally general, just to identify the key aspects of these analysers for the scope of this work, and are not related to any specific industrial solution.

3. The EN 14181:2014

The Standard EN 14181:2014 is intended to be *prescriptive* for all AMSs installed on stationary sources (like, e.g. waste incinerators, power plants, biomass generators, petrochemicals, etc.), as it's explicitly cited in many European Directives, like the 2010/75/UE on industrial emissions (integrated pollution prevention and control) or the 2000/76/EC on waste incineration.
The document divides the life on an AMS into 4 different steps:

- QAL1 (Quality Assurance Level 1): the AMS, intended as the full system (from the sampling point up to the final result) has to fulfil either general requirements (i.e. quality and safety requirements, availability, stability, sensibility) and specific requirement from the single application (like, for example, matrix of flue gas, interferents, imposed limits, type of installation, weather conditions, etc.).
  In order to obtain this goal, a complete evaluation of the expected performances shall be done on the base of a detailed engineering project of the system, using the mathematical formulations given by the Standard.
  The QAL1 process is complete only when if possible to assure, on the base of the AMS design, that the guaranteed uncertainty of the AMS is always below a certain quantity given by the Competent Authority
- QAL2 (Quality Assurance Level 2): once the AMS is designed, it must be installed. QAL2 cover initial technical verification of the hardware and software in order to verify the compliance with the design and, more important, the initial calibration of the system. It shall be ensured that AMS measurements are reliable with the relevant 'standard reference method' (SRM).
  For every pollutant or chemical compound of interest, the relevant SRM represents the only method 'legally binding' for the limit verification of that compound. Also, the limits present in the Directives are intended to be determined using only the relevant SRM, so only one SRM per compound is published by CEN. QAL2 process, therefore, has the goal to demonstrate the equivalence between the AMS and SRM results.
- QAL3 (Quality Assurance Level 3): If QAL2 is accomplished, AMS enters into 'normal service' and the QAL3 procedure starts; a continuous QA/QC plan shall be established by the plant owner in order to guarantee that AMS is fully operative in the time.
- AST (Annual Surveillance Test): finally, every year, an independent verification test is required to check the AMS situation in order to confirm QA/QC and maintenance procedure or to solve the non-conformities eventually raised.

It must be noted that in the EN 14181, the AMS is similar to a photographic machine, an apparatus that perform periodically measurements, totally time uncorrelated each other (i.e. with no correlation between one measure and the previous and the following ones).
Data acquisition, storage and validations are covered by the new EN 17255-1/2/3 Standards, and are not covered in this work.

4. The EN 15267-1/2/3:2009

The scope of EN 15267 Standards series is:

- The specification of requirements for the manufacturer's quality management system, the initial assessment of the manufacturer's production control and the continuing surveillance of the effect of subsequent design changes on the performance of the AMS. It also serves as a reference document for auditing the manufacturer's quality management system.

- The definition of the performance criteria and test procedures for the AMS. It provides the detailed procedures covering the QAL1 requirements of EN 14181 and, where required, input data used in QAL3.

5. E-nose as an AMS

The main characteristics that an AMS shall fulfill can then be summarized as follow:

- An AMS device is intended to be used for continuous legal use, so it must ensure reliability, integrity and data security
- It shall allow the calculation on its uncertainty budget on the measured values vs a SRM
- It shall allow an independent verification of its metrological capabilities

5.1 Reliability, integrity and data security

Considering the schemes of an e-nose given in Figure 1 and Figure 2, it must be noted that the very first part of them is, in effect, a multicomponent analyser, not different at all from ‘common’ emission and ambient air analysers. It hints at the necessity that all sensors and analytical sections of an e-nose have to be fully investigated in terms of measured compounds, detection limit, interferences, drift, stability, linearity.
In order to allow QAL1 and QAL2 evaluation, e-noses shall declare the performances of the entire system (sensors, data acquisition, processing, interfaces etc.) and permit their verification.
Also, in order to allow QAL3 procedures (the ongoing quality checks), it’s also necessary to have specific hardware and software solutions to implement periodic checks of the sensors array (Figure 3); the negative feedback is that in future it will be necessary to increase the complexity of this part of the systems, that often is very simple and reasonably cannot accomplish with certification requests; also it will take to higher prices of these units.

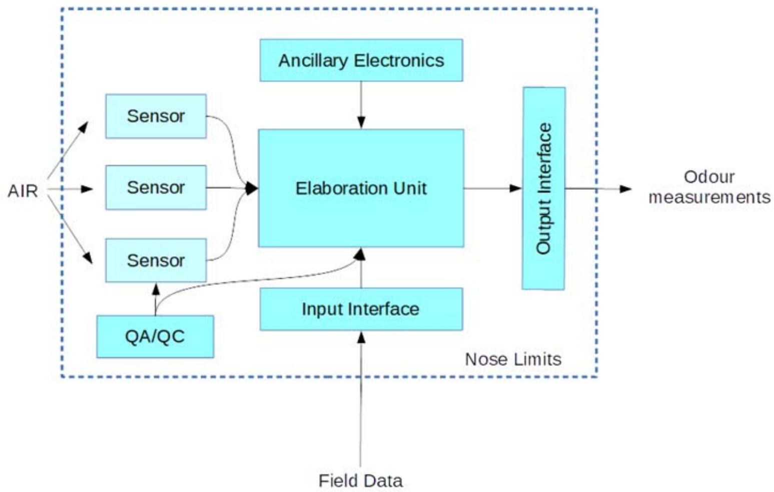

Figure 3: independent E-nose with QA/QC control of the sensor array

A different approach is necessary to consider the elaboration unit (see Figure 1). Hardware verifications are well-known and not very expensive, but software verification can be totally different.
One of the bigger advantage of e-noses is their extreme flexibility due to possible modification of the software, either using different algorithms, set up data and calibration data. Such flexibility can be very useful in term of obtaining a good QAL2, so that the e-nose can be trained to give results very near to the calibration values (that are ‘true values’ by definition); but it’s also one of the bigger problem during ongoing verifications, as every modification done after QAL2 process implies the formal invalidation of its performances. E-nose structure shall ensure that, when the calibration process is finished, all the software routines, calibration data, set up and all other the relevant configurations are locked and encrypted in order to guarantee performances changes and unauthorised modifications.
Normally any modification is allowed only during QAL2s, ASTs and under the control of the Competent Authority.

For example, in case of implementation of a neural network algorithm, the learning capabilities are obviously to be allowed during QAL2 process, but must be inhibited during normal operations in order to ‘freeze’ the system performances.
Such part of the software certification is very delicate, expensive and normally not implemented nowadays.
A good approach should be based on the possibility, during the calibration process, to produce a certain sets of raw data that can be used, during the ongoing verifications, as offline inputs to verify the output of the system.
Even more complicate is the case of a web based e-nose (see Figure 2) where the device itself is not able to accomplish all the necessary calculations internally. In this case, the system produces raw data that are sent via web to an external server that evaluates the final results, often interpolating data from many units. In this case the ‘functional’ limit of the e-nose accordingly to EN 14181 is well beyond its physical dimensions, as it’s necessary to include the web network and the external server. In effect, in this case the physical e-nose can be considered as a mere sensor array, and the real e-nose function is accomplished by the external server.
It’s clear that the idea to implement QAL1, QAL2 and QAL3 to a series of web servers is not simple and cheap, and could be virtually impossible to be reached.
Another important aspect is related to the possibility that the e-nose stores and manipulates measured data in order to evaluate averages, indexes or simply refine measurement algorithm: in this case the system is also considered an DAHS (Data Acquisition and Handling System), that shall fulfil requirements of new EN 17255-1/2/3. In this case, generally speaking, the software shall be certified by an external organisation and data treatments shall be securely stored and traceable, increasing the complexity of actual units.

5.2 Uncertainty budget

Nowadays all emission and ambient air monitors shall declare their ‘uncertainty budget’ evaluated following principles of the ISO IEC Guide 98-3:2008 (GUM 1995) “Guide to expression of uncertainty in measurement”. The way of evaluation typically implemented is what is defined by GUM the ‘Type B uncertainty evaluation’; in this case the output of the measuring process is described by the equation (1)

$$y = f(x_1, x_2, \dots, x_n) \tag{1}$$

The estimation of the total uncertainty $u(y)$ can obtained by the propagation of the single uncertainty terms for each x_i, $u(x_i)$, by the means of equation (2)

$$u(y) = \sqrt{\sum C_i^2 u^2(x_i)} \tag{2}$$

where C_i is the sensitivity coefficient of the single x_i term, and $u(x_i)$ its uncertainty.

Function *f* shall cover all the measuring process, from the single sensor acquisition up to the final output, including calibrations, interferences, nonlinearities and software related errors.
For such part, it could be very useful the use of a new CEN standard, the FprCEN/TS 17198:2017 “Stationary source emissions - Predictive Emission Monitoring Systems (PEMS) - Applicability, execution and quality assurance”.
Such standard is expressively designed for emission prediction models, but can be easily adapted to e-noses; furthermore, its scope is to achieve the conformity to EN 14181 and EN 15267 of software predictive systems and furnishes a simplified formula for uncertainty evaluation, that is (equation (3)):

$$u(y) = \sqrt{(u_{model}^2 + u_{input}^2 + u_{other}^2)} \tag{3}$$

where u_{model} is the uncertainty of the mathematical model, u_{input} the one from sensors array, u_{other} the one due to parameters not included into the model, evaluated by confrontation with independent odor measurements used to calibrate the e-nose.

5.3 Independent verifications

An e-nose used as an AMS shall give the possibility to the final user to verify its metrological capabilities, in order to validate its operational status and guarantee it’s calibrations are still aligned with QAL2 results.

In practice this means that, for example, a specific gas matrix should be realised and used in order to validate the system. It's not clear neither the number of compounds that should be present, nor their concentrations, as no real reference method is still available.

6. Conclusions

In conclusion, application of e-noses as Automatic Measurements Systems is a delicate and complicated process, not yet deeply explored, and where there is a continuous implementations of both e-noses and the relevant technical standardisation. Analysis of present documents, anyway, seems not to exclude, in future, a modification of the actual structure of e-noses in favour of new designs.

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