**Statements as agreed at the 3rd ISNS European regional meeting, Seville (Spain), November 2004**

1. Information for parents

1.1 Provision of information on screening is a responsibility shared by the screening program and health care professionals (midwives/pediatrician/nurse)

1.2 Provision of information about the screening program to professionals in charge of screening is essential so that they can pass it on to families.

1.3 The parents must be guided through the whole screening process. For each step, verbal as well as printed information (leaflets) must be given by a professional. This information should be such as not to alarm the parents. It should include screening objectives from a health care point of view, diseases screened for, sampling procedure, consent process (when applicable) and notification of the results

1.4 The optimal timing to provide the first information is during the prenatal period and should be repeated at the time of sampling. When applicable, give the families enough time before actual consent is requested.

1.5 Leaflets (or other material such as video/CD/DVD) should be available in different languages as to accommodate various ethnic backgrounds of parents.

2. Information to be recorded on filter paper card

2.1 Data should be entered only to identify the infant (name, sex, date of birth, gestational age, birth weight, unique health service identifier) as well as to facilitate tracing the child in case of indicated follow-up (either name of mother or contact person).

2.2 There is no need for data on ethnicity unless because of local circumstances (e.g. targeted screening). There is no need to record for written parental consent on cards, but should parents decline all or some of the tests offered then this must be clearly recorded.

3. Quality of the filter paper cards

Filter paper collection cards should be CE-marked. Expiry date must be established by independent party and should be uniform across Europe.

4. Sampling procedure

4.1 Incision devices are preferred over puncture devices, since they cause less pain to the infant.
4.2 No "pain relievers" are necessary, they may interfere with the analytical procedure. The presence of the mother is recommended.

4.3 Capillary blood is preferred over venous blood because of its simpler procedure.

4.4 No anticoagulants should be used since some of them have been shown to interfere with the analytical procedure.

5. Use of common terms

The terms in the ISNS lexicon must be used in publications on neonatal screening

6. Use of analytical units
The analytical results for non-protein analytes must be expressed in S.I. units per liter whole blood.

7. Packaging and sending of dried blood spot specimens
7.1 ISNS declares filter paper collection kit as primary container, high-quality bond envelope as outer container

7.2 DBS specimens should not be placed in hermetically sealed containers (plastic or plasticene envelopes
- Cover slip may be added
- In case of multiple cards, they should be rotated 180 degrees
- In case of multiple cards a glassine paper can be placed in between
- The cards may be enclosed in a high quality bond envelope
- Do **not** place a biohazard label
- Do **not** specify on the envelope that it contains biological material

Note: The UN committee on Transport has recommended (Nov 2004) to regard dried blood spot specimens as not being a health hazard; these specimens can be sent by normal mail without any special measures.

8. Storage of dried blood spot specimens before analysis
8.1 Dried blood spot specimens must be kept at room temperature for no longer than 2 days if they cannot be sent to the laboratory immediately
8.2 Dried blood spot specimens must be kept at room temperature in the laboratory awaiting analysis

9. Storage of dried blood spot specimens after analysis
9.1 If dried blood spot specimens are stored for possible retesting within the screening program (e.g. to check possible false-negatives) they can be stored with dessicant, up to 1 year, at less than 6 C (preferably at -20 C), with an ID linked to the patient data.

9.2 If dried blood spot specimens are stored for non-anonymous research they can be stored with dessicant, at less than 6 C (preferably at -20 C), with an ID linked to the patient data. Informed written consent must have been obtained prior to the use of the cards

9.3 If dried blood spot specimens are stored for anonymous research they can be stored with dessicant, at less than 6 C (preferably at -20 C), without any identifier. The approval of an ethical committee is needed prior to the use of the cards.

Note 1: if only DNA-testing is envisaged the cards can be stored at room temperature.
Note 2: local regulations will determine the minimum and maximum storage period

9.4 Disposal of dried blood spot specimens must follow local rules for biological material, usually through incineration.

10. Epidemiological evaluation of screening programs
It is necessary to determine the minimum set of feed-back information to screening programs needed for the evaluation of their clinical effectiveness, such as coverage, quality of the specimens, analytical quality, short-term and long term follow-up.

Note: See ISNS Lexicon for definition of epidemiological parameters.