Attachment 19 rev: Proposed proficiency materials

The proficiency materials should include at least one powder, one massive non-embedded and one massive embedded, to match the physical forms of the test materials. The list should be short (N=6 to 10). These materials will be stable over time and include examples of high and low metal releasing materials. A physical repository of proficiency materials will be set up. Full characterisation of the samples will be sought from sample provider or by performing appropriate physico-chemical tests. Once the SOP is approved, the materials will be initially tested at least 10 times and in at least two separate labs using the gastric fluid SOP. Shewart charts will be created and made publicly available. Examples of possible materials are provided below.

Massive non-embedded

Lead shot (CAS 7439-92-1): 99.9995% trace metals basis ; 1 mm,

Nickel metal (CAS 7440-02-0): 99.9% Ni (Materion Advanced Chemicals Inc. [formerly Cerac]; 1.1 ppm Co, Cylinders: 3.1 mm diameter x 3.35 mm long; surface area: 47.7 mm^2 per pellet

Massive embedded

SS316 sheets: Outokumpu Pte (Finland) 68.1% Fe (balance), 16.2% Cr, 11.2% Ni, 2.27% Mo, 1.10% Mn, 0.65% Si, 0.25% Cu, ≤0.18% Co, 0.12% Al. Squares: 10 mm x 10 mm x 2 mm.

Brass rod CW602N: Wieland (Germany)

Powders

Cobalt metal (CAS 7440-48-4)

Copper slag (to be further defined)