

(See [CH\(04\)01](#))

**DIRECTIONS GIVEN UNDER THE
HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990**

Directions on Reporting Adverse Incidents

Ref: D2004/3

These Directions are

GENERAL DIRECTIONS

Section of the Act providing
for these Directions

Section 12(d) and (g) of the 1990
Act

These Directions are deemed
to have taken effect on:

1st March 2004

These Directions remain
in force:

Until revoked

1. Each licensed centre must report all adverse incidents (see 3 below) to the HFEA. The Person Responsible (PR) or senior colleague in the PR's absence must notify the Director of Regulation or nominated representative by telephone that a clinical incident has occurred or has been identified as having occurred within 12 working hours of the identification of the incident. The call should provide the following information
 - Name of Centre (HFEA Centre Number)
 - Location where the incident occurred
 - Brief details of the incident
 - Whether patient, embryo, gamete or staff safety has been compromised
 - Name of centre or clinic staff responsible for liaising with the HFEA
 - Contact details including out of hours arrangements
2. Each licensed centre must complete and submit an Incident Report Form as set out in the Schedule to these Directions. PRs or senior colleague in the PR's absence must follow up the initial telephone call with a completed report form faxed to the Director of Regulation within 24 working hours of the incident. A copy of the form must also be posted to the Director of Regulation. The form should also be copied to the Nominal Licensee of the centre.
3. Adverse Incidents are defined as any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and / or gametes, or to staff or a licensed centre. All breaches of the HFE Act and / or breaches of the HFEA *Code of Practice* must be reported as adverse incidents to the HFEA

Date: 8th January 2004

Suzi Leather
Chair