I. Regulatory Regime under the Private Health Facilities Act
NSW private health facilities are regulated under the Private Health Facilities Act 2007 (PHFA). The PHFA establishes a licencing regime, with licensing standards covering a range of areas, including medication management, blood and blood products and infection control. Standards are applied to facilities depending on the nature and type of service they provide.

The PHFA incorporates a requirement for facilities to notify the Ministry of Health (MoH) of “reportable incidents” within 48 hours. Regulatory tools available under the PHFA include investigation and inspection, directions to take remedial action and stepped sanctions for non-compliance.

II. Incorporation of National Standards into existing Regulatory Regime under the Private Health Facilities Act
Three elements support NSW regulatory oversight of implementation of the National Standards in NSW private health facilities:

1. The terms of the National Standards are generally paralleled in the NSW regulatory regime and Licensing Standards, so that they will be covered by existing NSW regulatory systems;
2. A condition is imposed on each licensed private health facility requiring engagement by all licensed facilities in the National Standards and the Accreditation Scheme;
3. Under arrangements agreed between NSW MoH and the Australian Commission on Safety and Quality in Health Care (ACSQHC), NSW MoH (as the NSW regulator) receives data on the outcomes of accreditation processes related to private facilities licensed under the PHFA, enabling NSW MoH to respond to emerging issues and oversee compliance.

The following arrangements are in place between MoH, ACSQHC and accrediting agencies.

III. Action in response to Accreditation Surveys
- Where a survey identifies a “not met” item the accrediting agency will provide the NSW MoH with a copy of the Survey Report and Recommendations at the same time as these are provided to the ACSQHC. Facilities are given 90 days to address any “not met” actions before a final determination on accreditation is made. NSW MoH does not receive reports where there are no “not met” items;
- NSW MoH will review the report and “not met” items and assess for potential breaches of the PHFA/licensing standards and respond appropriately. Options include:
  - Formal request for response from the licensee on the accreditation outcome;
  - Require the licensee to provide an action plan with timeframes to address the survey report recommendations;
  - An inspection of the premises;
  - Review any actions taken by the licence to rectify the issues;
  - Monitor implementation of the strategies addressing the report recommendations/risk.
- If, at the end of the 90 day NSQHS period, the facility has not addressed the “not met” items and therefore an informal notice of non-compliance is issued, this will also be provided to the NSW MoH, at which time a further review as to what if any state regulatory action is required to be undertaken.
• If the facility remains non-compliant after the 90 day period, in addition to the options outlined above, the NSW MoH may also consider (depending on the seriousness of the non-compliance issue):
  - Imposition of additional licence conditions/variation of conditions;
  - Suspension or cancellation of licence or restrictions on licensed class.

IV. Action in response to Notification of a “Significant Risk”
• Where an accrediting agency identifies a “significant risk” in the course of a survey they will notify the NSW MoH within 48 hours;
• The NSW MoH will treat the notification as a “reportable risk” under the PHFA, and assess accordingly. Options include:
  - Formal request for response from the licensee on the accreditation outcome;
  - Require the licensee to provide an action plan with timeframes to address the survey report recommendations;
  - An inspection of the premises;
  - Review of any actions taken by the licensee to rectify the issues;
  - Monitor implementation of the strategies addressing the report recommendations/risk.
  - Imposition of additional licencing conditions/variation of conditions
  - Suspension or cancellation of licence or restrictions on licensed class