

Keyword	module	design
	manufacturing	quality assurance
Directive refere	Annex III Module H	Annex III Module H1

Adopted by CLAI

14/11/1996

Subject: Conformity assessment - Application of modules H and H1

Question: Is it possible to apply a module H or H1 when the design and the manufacturing are made by two different entities independent from each other within a same industrial group, each of the entities having a quality system in accordance with the specifications of the directive ?

Answer: It seems possible for the application of a module H as for the application of a module D or E to "subcontract" a part of the operations subject to the control (by inspections or by a quality assurance system).

In a same industrial group, we can imagine that a notified body examines the quality systems and audites in parallel the department responsible for the design and the department responsible for the manufacturing but in any case, there shall be a **UNIQUE RESPONSIBLE** for the conformity to the directive for the concerned equipments, who has authority on the two departments.

Modifications compared to the previous adopted version : Editorial correction on 2004-09-16.