From: Toth-Allen, Jean
Sent: Wednesday, November 01, 2006 2:26 PM
To: [purged]
Subject: Alarmed access

Dear Mr. [purgted];

Your inquiry was forwarded to us for a response.

There are no FDA regulations that I am aware of that require access to a hospital unit, even if involved in FDA-regulated research, to be alarmed. However, for studies with pharmaceuticals that are considered to be "controlled substances," there is the requirement that they be secured against theft and/or illegal diversion. It might be with regard to such product containment that the investigator who inspected your site referred to alarmed access.

This requirement is specifically found in Title 21, Code of Federal Regulations (21 CFR) 312.69. (Current CFR references are most easily accessed through http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm.) This regulation states:

"If the investigational drug is subject to the Controlled Substances Act, the investigator shall take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution."

If you are interested in the basis for FDA requiring that controlled substances be so contained, useful general information about the U.S. Federal Controlled Substances Act can be found at http://en.wikipedia.org/wiki/Controlled_Substances_Act.

Hope this information is useful. If you need further information and/or have additional questions, please submit them to the official GCP mailbox, gcp.questions@.fda.hhs.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Good Clinical Practice Program
OSHC, Office of the Commissioner, US FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [purged]
Sent: Friday, October 27, 2006 9:40 AM

To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: Hello.

I'm clinical study coordinator in a Clinical Research Organization in FRANCE.
Further to an audit, we indicated us that the inspectors of the FDA recommended that access to an hospitalization unit must be under alarm control. I do not succeed in finding a text FDA in connection with access controled to clinical unit.
Would have you please the reference of text in touch with this point?
Thank you very much for your help.

[purged]