

Envelope-to: hammond@sunshine-project.org
Subject: IBC Meeting Minutes from IOMAI Corporation
Date: Wed, 25 Oct 2006 14:28:31 -0400
Thread-Topic: IBC Meeting Minutes from IOMAI Corporation
thread-index: Acb4Y1+dOHDPv2XzRxi0Y294zN9MFw==
Priority: Urgent
From: "Narayan Iyer" <niyer@IOMAI.com>
To: <hammond@sunshine-project.org>

To
Edward Hammond
The Sunshine Project
PO Box 41987
Austin TX 78704 USA

From:
Narayan Iyer, Ph.D.
Chairman, Institutional Biosafety Committee (IBC)
IOMAI Corporation

Sub: IOMAI IBC Meeting Minutes as requested

Mr. Hammond:
As requested in your fax letter dated 12 October 2006, please find attached 2 (two) documents covering the IBC meeting minutes held at IOMAI Corporation.

Sincerely,
Narayan Iyer Ph.D.
Chairman, Institutional Biosafety Committee
IOMAI Corporation
20 Firstfield Rd
Gaithersburg MD20878
Tel: [301-556-4533](tel:301-556-4533)
Fax: [301-5564503](tel:301-5564503)
Email: niyer@iomai.com

Content-Type: application/octet-stream;
name="24June05_IOMAI IBC minutes Published.pdf"
Content-Description: 24June05_IOMAI IBC minutes Published.pdf
Content-Disposition: attachment;
filename="24June05_IOMAI IBC minutes Published.pdf"

IOMAI Corporation
Confidential Information

IOMAI Corporation
20 Firstfield Road
Suite 250
Gaithersburg, MD 2087

Minutes of Institutional Biosafety Committee Meeting
June 24, 2005

Members attending:

Narayan Iyer – Chair

Jeff Blake

Bo Anderson

Bruce Donato – Community Representative

Darrell Fickett – Community Representative (conference call)

Guest attending:

Merv Hamer – IOMAI Corporation

Kim Harvey – IOMAI Corporation

IBC Overview Presentation

A presentation was given on the duties and authority of IBC's by Bruce Donato. It was a composite of 2 different NIH presentations given in 2003. The following discussion was held concerning IOMAI's IBC:

- A “change of protocol” (slide 6) was defined as anything significant in the opinion of the chair of the IBC.
- It was proposed that Kim Harvey become a registered/voting member of the IBC. **This will be discussed with IOMAI management by Narayan.**
- In order to inform the public of the IBC, it was proposed that the web site indicate that an IBC exists and to contact the company for information on meeting schedules and/or minutes. If minutes were to be sent out, they would need to be reviewed for confidential information prior to release. **This will be discussed with IOMAI management by Narayan.**
- A three level system was proposed for the authority of the IBC as shown in Table 1. Only pilot plant processes would be reviewed by this IBC.

**IOMAI Corporation
Confidential Information**

- The process for requesting approval was discussed (**draft to be developed by Bruce**). The agreed method was for the requestor to send a “form” to the chair. The chair would determine the level of approval needed and forward it as appropriate for review.

TABLE 1 APPROVAL GRID		
EXEMPT	CHAIR APPROVAL	FULL IBC APPROVAL
< ■ liters	Small protocol changes	Any new strain, organism, or recombinant DNA introduced which will be greater than ■ liters.

Process Review

Jeff Blake reviewed the proposed process. The following items were reviewed:

ACCESS TO PILOT PLANT

- How was access to the pilot plant going to be controlled?
 - Employees must go through a training, then they are admitted under supervision until it is deemed they understand the requirements, at which point they are approved to enter.
 - Card access is not granted until the 3rd level is achieved.
 - Visitors are only permitted in when escorted and the pilot plant is in the “inactive” mode.
- **Narayan will send copies of the visitor and gowning policies to IBC members.**
- It was suggested to review a waiver and confidentiality agreements for visitors into the pilot plant.

DECON PROCEDURES

(Note: The decon procedures were still being developed.)

- The initial agent was classified with GRAS status.
- Typical decon procedures were considered to work. Narayan will provide literature to this effect to the IBC.

IOMAI Corporation
Confidential Information

- The DECON procedure should separate out decontamination of equipment from waste products because the current wording is ambiguous.
- The proposed waste system was a [REDACTED] gallon container that would be mixed and open to the atmosphere ([REDACTED] catalog number [REDACTED] Vessel). It was agreed that a closed bio-dome system with a filtered vent would be used.
- Darrell proposed using a [REDACTED] system utilizing a stir bar or recirculating pump for mixing. This idea may be explored later if needed.
- Concern was expressed over aerosol generation from the centrifuge and homogenizer. This was tabled until the next meeting because the first run will have these processes completed on a smaller scale in R&D. The transfer of material to R & D will be less than [REDACTED] liters in secondary containment. This will be package in a “closed” system.
- Jeff will send the IBC specs on the proposed centrifuge and homogenizer.
- The IBC members will do a walk-through the facility to discuss methods to minimize aerosol generation. (NOTE: Not required for the July run.)

EMERGENCY RESPONSE

- Removing clothing should clearly indicate that it is the Tyvek® overalls and not stripping down naked.
- **Narayan will send out documents detailing exposures/symptoms of the agent.**
- **Bruce would look at the CHP and see what it states on spill response** (From the CHP: Spill Response
 - Unless you are properly trained, spill response should not be attempted.
 - Notification of a spill should be conducted according to site-specific policies.)

GENERAL

- **Narayan and/or Jeff will email pertinent SOP's to IBC members.** Members should “reply all” when making comments.
- Narayan will set up a meeting including a tour for the 2nd half of July when members are expected to be in town.

IOMAI Corporation
Confidential

IOMAI Corporation
Institutional Biosafety Committee Meeting
07 June 2006

Published Meeting Minutes

Attendees:

Members: Bo Andersen, Jeff Blake, Bruce Donato, Darrell Fickett (over phone) and Narayan Iyer

Participants (in absentia): Kim Harvey and Merv Hamer

1. Objective Review of the Annual Update on Past Performance of Fermentation, Containment and Decontamination Status:

- i. The Committee had received the status report (for period of a year ending June 2006) about a week earlier for review. The status report provided the Background information, Procedure followed, a summary of the fermentation runs executed at the facility and the amount of biowaste processed.
- ii. No adverse situations were observed.
- iii. Interactive discussion highlighted the aerosol containment method during post-centrifugal harvest of the cell slurry was effective.
- iv. The current system has been found to be compliant and adherent to the Biosafety principles

2. Discussion / Recommendations:

- i. The Committee recommended a confirmation test of the decontamination method be executed. A simple assay design was suggested involving collecting an untreated sample of the biowaste to be tested in parallel to the decontaminated/ treated biowaste for absence of microbial growth. Positive growth in the untreated sample will demonstrate that the decontamination method is truly effective.

Action Item:

- A. Jeff Blake to collect sample before the next biowaste inactivation process and provide it as a control sample to QC for microbial testing.
- ii. The Committee recommended that a procedure be adopted that would allow a simpler and efficient traceability of the microbial testing data generated on the decontaminated biowaste conducted by the QC group.
At present, test data is documented and stored as part of the QC test reports

IOMAI Corporation
Confidential

and held by the QC Manager. A simple step of providing a copy of the testing report (along with the communication of lack of microbial growth in the treated biowaste) was considered sufficient.

Action Item:

- A. Jeff Blake / Narayan Iyer to communicate the request to QA/ QC and ensure the procedure is instituted such that a copy of the testing data is available as part of the batch record.
- iii. The IBC recommends that Iomai procedures be formalized before new organisms are introduced as part of new projects. The Committee would like to be aware of new organisms planned to be introduced into the facility. A simple document covering the name, source, the safety level, the anticipated use and containment in place may be submitted to be circulated with IBC members. A simple form covering such relevant information will be developed by the IBC and key Iomai representatives would be made aware and trained on the use of the form.
- iv. Request for Meeting Minutes from External Organizations:
It was reported by Narayan Iyer to the IBC that recently, requests from a non-profit organization (Sunshine Project US, a 501(c) 3) had been received requesting for access to the Iomai's IBC meeting minutes. The NIH guidelines, Clause Section IV-B-2-a-(7) states *"Upon request, the institution shall make available to the public all IBC meeting minutes"*.

The IBC discussion lead to the following recommendations:

Action Items:

- A. Narayan Iyer as IBC chair to communicate and share redacted (if necessary) 'meeting minutes' with external parties who formally request the information. Documents to be verified for absence of any proprietary information.
- B. Note: Documents like the status report will not be sent to any outside parties.
- C. Response to questions requesting Information about 'implementation of policies' is not mandatory.