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20 November 1985  
ENGLISH

Viet Nam.

PILOT PRODUCTION OF MEDICINES USING  
INDIGENOUS RAW MATERIALS . ]

DP/VIE/80/032

~~SECRET~~

Technical report: Layout and building requirements for the pilot plant\*

Prepared for the Government of Viet Nam  
by the United Nations Industrial Development Organization,  
acting as executing agency for the United Nations Development Programme

Based on the work of I. Száva,  
Civil Engineer Consultant

United Nations Industrial Development Organization  
Vienna

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I. INTRODUCTION

The UNDP project supports the establishment of a pilot plant as an essential facility of improvement in formulation, research, process monitoring and production technologies of the traditional plant based drugs. The pilot plant facility is setting up at the Institute of Materia Medica in Hanoi.

The duties of the Civil Engineer Consultant were as follows:

1 - To study the present existing buildings and give recommendations for remodelling if they do not meet the technological WHO/GLP requirements

2 - To study the existing drawings and designs and give recommendations for changes if they do not meet the above requirements

3 - To give all of the specifications for the detailed mechanical and engineering design of the building with special consideration to the specification of public utilities and essential services, such as electric supply, air-conditioning equipment, etc.

4 - To up-date the project document if recently any new element emerge which seems to be important to incorporate.

During the days spent in Viet-nam it was possible for the civil Engineer Consultant to collect information, to discuss with relevant officials, to visit the farm of the Institute Materia Medica and to prepare drawings which contain all the recommendations and specifications for changes as prescribed in his job-descriptions.

## II. CONCLUSIONS AND RECOMMENDATIONS

The Civil Engineer Consultant in close cooperation with Dr. C.K. Atal, JCA of the project studied the existing buildings and designs. He examined the possibilities to place the pilot plant and the related units.

They came to the conclusion:

1 - the pilot plant area in the existing building is to separate from the other parts of the Institute,

2 - modifications must be made in the buildings and in the existing designs to meet as far as possible the requirements of the WHO/GMP specifications.

The annexures 1-7 contain all the specifications needed to prepare the detailed drawings of the buildings.

Two sets of these drawings have already been provided to the Institute of Materia Medica in Hanoi. This was acknowledged by the relevant officials who have signed the drawings as an expression of their total agreement.

The set of seven drawings which form a part of the Consultant's terminal report supersede the drawings given in annexures 4-7 of the Project Document, Number DP/VIE/80/032.

The Institute of Materia Medica must adhere to the detailed requirements given in the drawings as also agreed by them during discussions. It is recommended that UNDP should also ensure through an inspection by a competent consultant that the modifications and specifications recommended have been fully implemented before installation of machinery and equipment. The verification operation could be inserted in the work plan chart.

There are no obstacles to begin the work for housing the batch extractions, the tableting and liquid preparation sections, to make the modifications in the buildings for animal house and benches-scale laboratory, to erect the steel framework for the continuous extraction and hydrolyser equipments,

to realise the new building on the farm for the post-harvest technology operations. On the work plan chart in the Project Document the above mentioned activities are shown by the lines "c" and "d".

### III. LAYOUT AND BUILDING REQUIREMENTS FOR THE PILOT PLANT

The Institute of Materia Medica, has its main research and development laboratory building located in the centre of Hanoi city besides a number of farms and branches located in other provinces of Viet-nam. For the purpose of UNDP support to this institute we are mainly concerned with the main laboratory building at Hanoi and one of the farms located on the outskirts of Hanoi city. The main laboratory campus consists of a three story building which is at present used for R + D activities on a laboratory scale. In order to meet the demand of space and building for the proposed pilot plant, the Institute has planned to shift the entire ground floor existing activities, providing the scientists alternate laboratory facilities on the first and second floors. Besides making available the total ground floor for housing the pilot plant, the institute has also placed at the disposal of the project a row of sheds along the southern boundary wall to provide space for workshop, repair and

maintenance, animal house, raw material stores and other auxiliary activities associated with the pilot plant. An unconstructed area in the North East corner of the Institute enclosure has been allotted for solvent storage. A shed along the North periphery of the Institute is to be dismantled to provide new ground for the phase II pilot plant for production of steroids. A large hall on the third floor Northern wing of the main building has been earmarked for housing all glass bench-scale apparatus for laboratory scale processes for manufacture of phytochemicals and for chemical modifications of phytochemicals.

UNDP support also envisages providing technical support to create facilities for scientific drying of the medicinal plants grown at the farm near Hanoi and to create a seed storage facility at the farm. At present the farm has only one shed which houses the office of the farm manager and a meeting room besides a few dilapidated buildings. However the institute has planned construction of a new building, a plan of which has been duly approved by the government and budgeted as government input to the UNDP project.

The main task of the Civil Engineer Consultant therefore was suggest suitable modifications



consistent with the technical functional requirements of the project.

The task of the short term Civil Engineer Consultant could thus be classified into the following.

A/ Main laboratory building

a/1 - Suggesting alterations, modifications to the ground floor South-wing to locate tablet manufacturing unit and liquid products blending and packing units, keeping in mind the principals of good manufacturing practices as defined by WHO to the maximum extent possible, under the practical limitations of Viet-nam and the Institute of Materia Medica.

/2 - Suggesting modifications to the South-wing for providing suitable floor space and safety and hygiene standards for manufacture of aqueous and alcoholic extracts and their concentrates.

/3 - To suggest proper storage requirements and office space in the central wing.

b/1 - Modification, alteration of corridors and construction of new trolley-tracks to define the movement of personnel and materials to ensure good manufacturing practices.

/2 - Modifications to washroom, toilets and WC facilities to improve standards of hygiene, cleanliness and clean environment.

/3 - To provide dust-free, humidity-free environment those rooms in which it was necessary and to provide facility for clean-room operations providing arrangements for change of laundered and disinfected aprons and masks.

c/ - Modifications to the third floor bench-scale hall and to provide proper base and support to large sized glass equipment with safety standards particularly to prevent possibility of fire.

B/ South boundary sheds.

To propose proper lay out of auxiliary facilities such as laundry, glassblowing, mechanical and electrical repair and maintenance shop, animal house and storage of farm produced disintegrated raw materials.

C/ North boundary.

To design a new building to be constructed in Phase VI should take into account the safety standards against fire hazards in view of use of petroleum solvents. Also to design a compact four storey structural framework to house continuous extraction unit.

D/ Farm building

Suggesting proper modification of the proposed new building for improved utilisation of space to match the functional requirements.

IV. DAILY DIARY OF THE CONSULTANT

- 30.Sept. 1985 - departure for Vienna  
briefing by UNIDO Project Personnel  
Recruitment Section
- 1.Oct. 1985 - briefing by UNIDO Industrial  
Operations Division
2. - briefing by UNIDO Substantive Officer  
- departure for Bangkok
3. - stopover in Bangkok
4. - departure for Hanoi
5. - discussion with CTA of the project
6. - Sunday
7. - preliminary meeting in the Institute  
of Materia Medica  
- reporting at UNIDO Office
8. - meeting in the Institute, discussion  
of the layout  
- drafting the proposed arrangements
9. - discussing in the Institute the  
requirements of tableting and  
liquid preparation sections  
- drawing the modifications
10. - discussing the batch-extractions  
section  
- drawing the modifications
11. - discussing the animal-house and  
bench-scale laboratory

12. Oct. 1985 - meeting for recapitulation of the requirements to give a final shape to drawings
  - drawing completion
13. - Sunday
14. - meeting with Vice-Minister of Health and staff of the Institute
  - drawing
15. - visit to experimental farm and discussion of building programme
16. - meeting in the Institute and discussion of the farm-building
17. - meeting with relevant officials of the Ministry of Building Committee and the staff of the Institute
  - after discussion they accept the requirements and modifications
18. - discussion of continuous extraction-building
  - drawing
19. - Saturday
20. - Sunday
21. - discussion of continuous extraction-building
  - drafting of report
22. - meeting with the Vice-Minister of Health

- 22. Oct.1985 - final meeting in the Institute and clearance of the final drawings by CTA and agreement of the counterpart
  - reporting at UNIDO Office
- 23. - departure for Bangkok
- 24. - drafting of report
- 25. - preparation of report for submission to UNIDO
- 26. - departure for Vienna
- 27. - Sunday
- 28. - debriefing by UNIDO Industrial Operations Division
- 29. - debriefing
- 30. - departure for Budapest

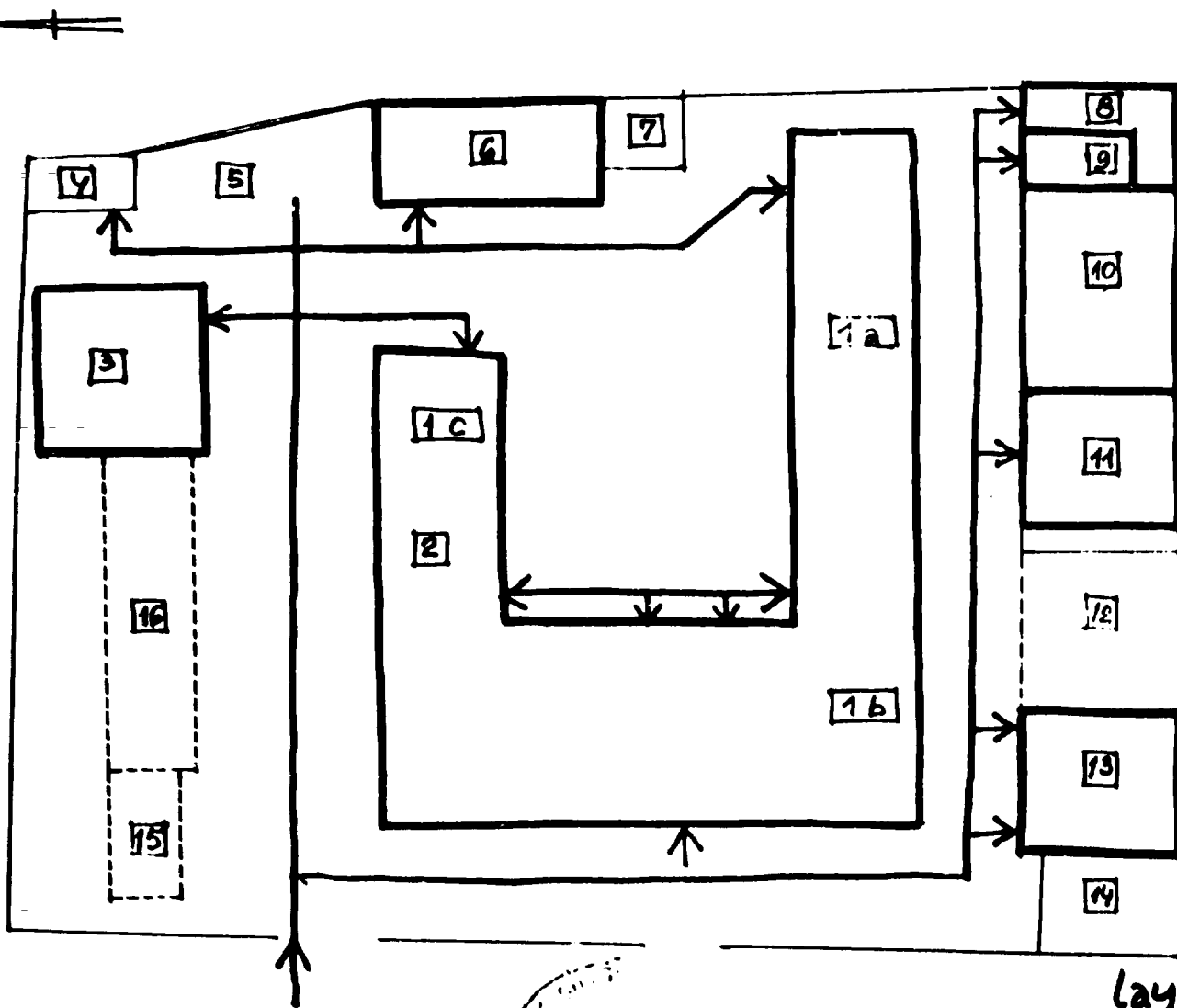
V. PARTICIPANTS AT THE MEETINGS

Professor Dr Nguyen Van Dan	Vice-Minister of Health
Professor Dr Doan Thi Nhu	Director of Institute of Mate-ia Medica
Dr Pham Duy Mai	Vice-Director
Dr Le Tung Chau	Vice-Director
Mr Truong Canh	Vice-Director
Mrs Khuong Bang Tuyet	Chief of Planning Sect.
Mr Vu Quoc Linh	Building Engineer
Mr Tran Toan	Manager of the farm
Mr Nguyen Phu Duc	Building Engineer
Mr Nguyen Tuong Dung	Intern. Relations Sect.

VI. ACKNOWLEDGEMENTS

The Consultant gratefully acknowledges

- the guidance received from the  
Chief Technical Adviser  
of the project,
  
- the cooperation given by the  
participants of the Institute  
of Materia Medica  
at the meetings,
  
- the efficient services of the  
interpreter .



- 1 - main building ground floor
  - 1a - tableting unit
  - 1b - liquid unit
  - 1c - batch-extractions
- 2 - main building third floor  
- batch-scale laboratory
- 3 - continuous solvent extraction and hydrolysis unit
- 4 - existing chemical-store
- 5 - solvent storage in barrels
- 6 - boiler house and coal-store
- 7 - water supply
- 8 - laundry
- 9 - glass blowing room
- 10 - maintenance and repair 'op
- 11 - animal house
- 12 - 13 - 14 temporary building units
- 15 - store for desintegrated material in sacks
- 16 - garage

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 INSTITUTE OF  
 MATERIA MEDICA  
 HANOI

annex 1

lay out of the pilot-plant and  
 related building requirements



*Atal*  
 Chief Technical Adviser

*UNIDO*  
 Dr. C.K. Atal  
 Chief Technical Adviser

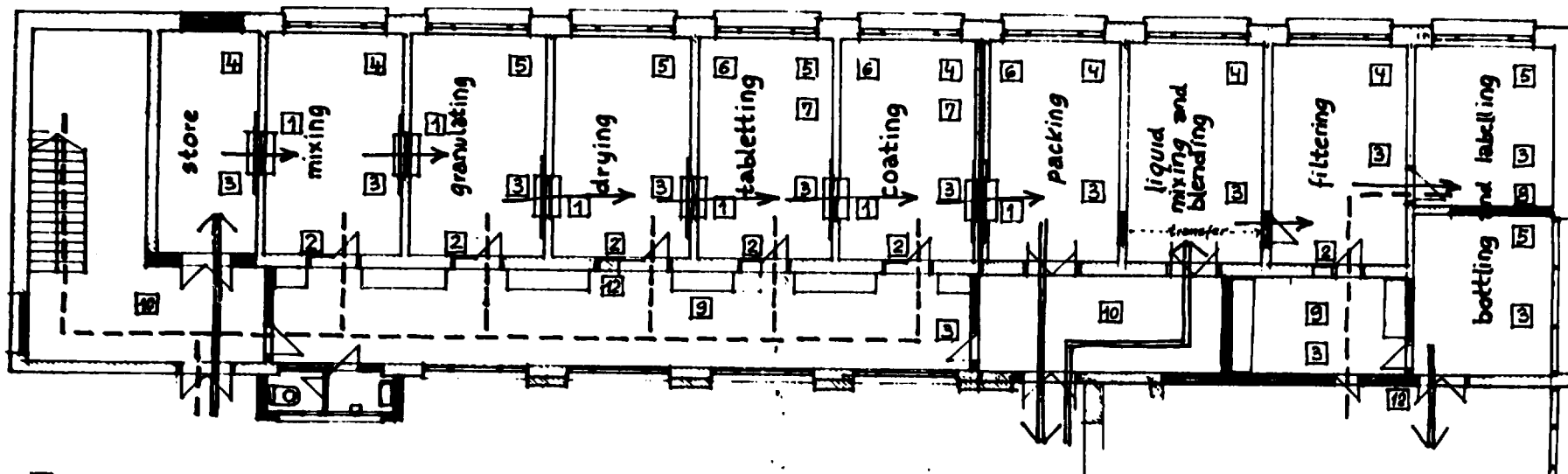
*J. Szava*  
 J. Szava  
 Civil Engineer Consultant



→ trolley-track  
→ material flow

----- personnel movement

■ new wall  
▬ opening



- 1 material handover openings 700/1000 panapet. 900; closed by sliding glass sash-windows; window counter projecting both sides 200 -
- 2 permanent fixing one door-panel in closed position; blocking wall openings above the door -
- 3 PVC sheet flooring heat fused to seal the gaps and upturned at the floor-wall angles - or terrazo flooring -
- 4 room walls to be covered with glazed tiles upto 1200 height; remaining portion of wall and the ceiling to be re-surfaced with washable paint; all door and windows to be repainted -
- 5 same as 4 but tiles upto 1800
- 6 window panels to be permanently fixed in the closed position. Replace broken and missing glass -

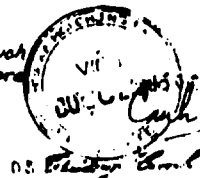
- 7 dehumidified/filtered air ventilation and maintain positiv air-pressure -
- 8 wall opening between two rooms to prevent change of accidental mislabelling -
- 9 corridor to strictly serve movement only of personnel working in tablet, respectively in liquid section; restriction on unauthorized entry - all workers to wear clean laundered white aprons and shoes - provide clean painted cloth-racks and shoeshelves in the corridor -
- 10 trolley must move only along trolley-tracks -
- 11 in all rooms electrical wires, switches and fittings are to conform to material standards and safety regulations -
- 12 prescribed fire fighting equipment, such as sand buckets, foam extinguishers and to be placed in the corridor -

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annex 2

INSTITUTE OF MATERIA MEDICA  
HANOI  
existing building  
ground floor  
part 1.

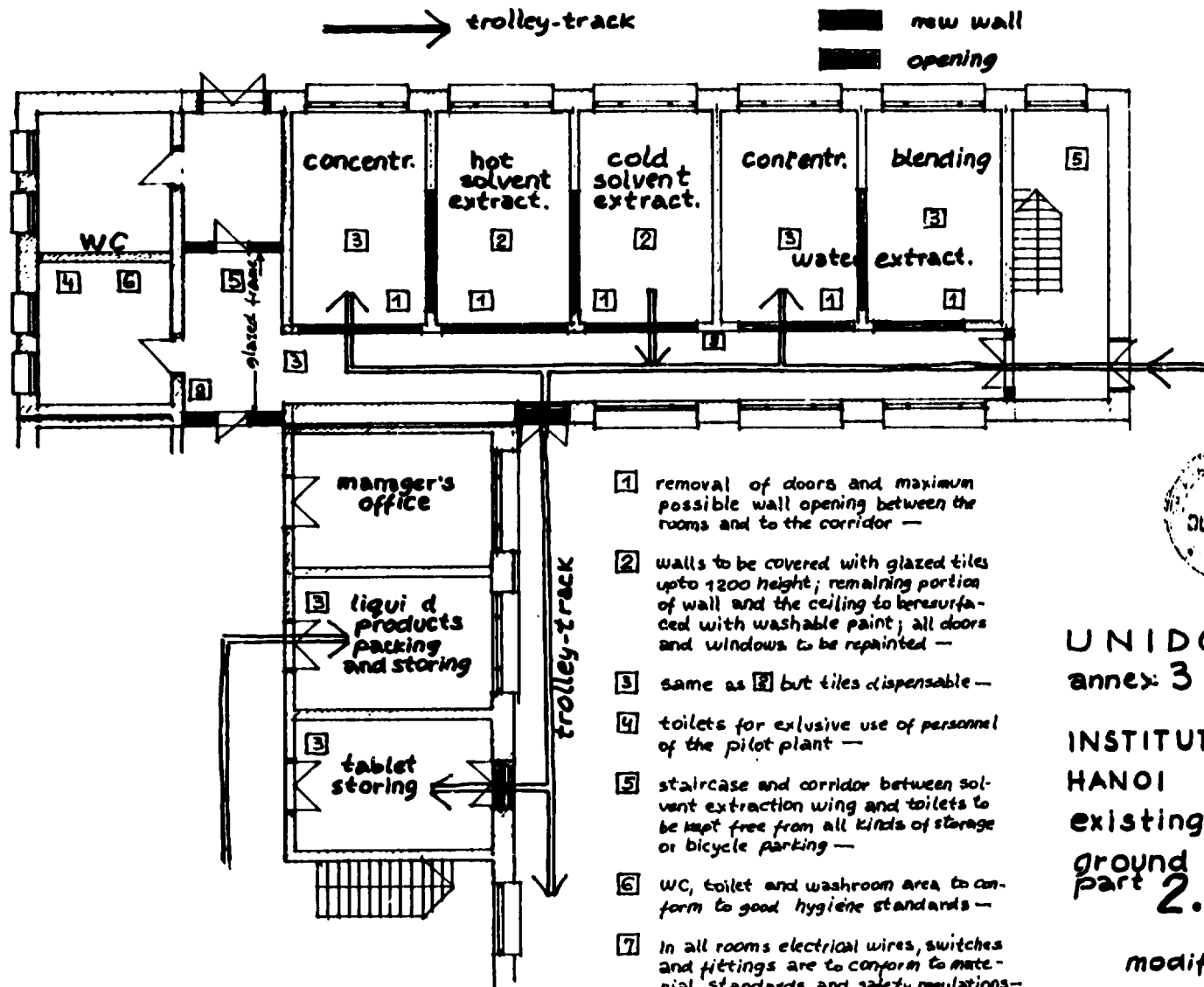
185 OCT.

modifications

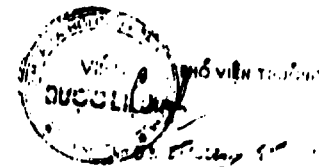


Dr. C.K. Atal  
Chief Technical Adviser

I. Száva  
Civil Engineer Consultant



- ① removal of doors and maximum possible wall opening between the rooms and to the corridor —
- ② walls to be covered with glazed tiles upto 1200 height; remaining portion of wall and the ceiling to be resurfaced with washable paint; all doors and windows to be repainted —
- ③ same as ② but tiles dispensable —
- ④ toilets for exclusive use of personnel of the pilot plant —
- ⑤ staircase and corridor between solvent extraction wing and toilets to be kept free from all kinds of storage or bicycle parking —
- ⑥ WC, toilet and washroom area to conform to good hygiene standards —
- ⑦ in all rooms electrical wires, switches and fittings are to conform to material standards and safety regulations —
- ⑧ prescribed fire fighting equipments, such as sand buckets, foam extinguishers are to be placed in the corridor



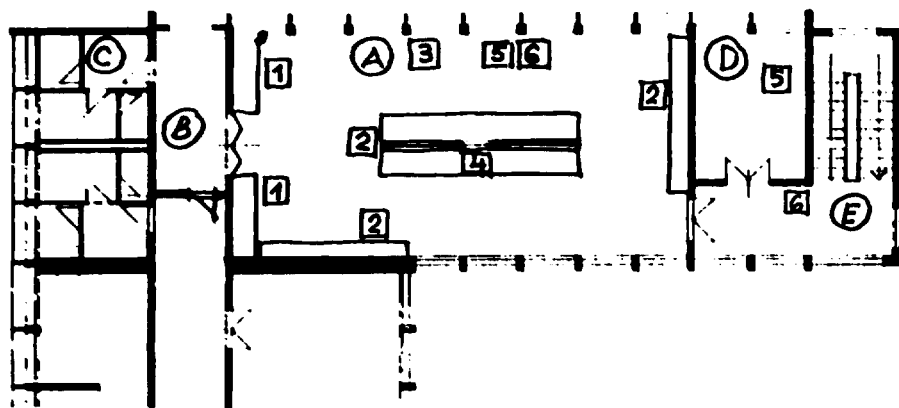
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annex 3

INSTITUTE OF MATERIA MEDICA  
HANOI  
existing building  
ground floor 4100  
part 2.

modifications 185. OCT.

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Dr C. K. Atal  
Chief Technical Adviser

*Szava*  
I. Száva  
Civil Engineer Cons.



6 - prescribed fire fighting equipment such as sand buckets, foam extinguishers are to be placed;

- (B) corridor strictly to serve movement only of personnel working in the bench-scale laboratory;
- (C) toilet and washroom are to conform to good hygiene standards;
- (D) substore for small quantities of chemicals; definitely not to be used for bulk storage of solvents;
- (E) staircase to be kept free from all kinds of obstruction.

(A) Bench-scale laboratory

- 1 - benches;
- 2 - frame for glass-apparatus and instruments;
- 3 - walls to be covered with glazed tiles upto 1800 height; remaining portion of walls and the ceiling to be surfaced with washable paint; all doors and windows to be repainted;
- 4 - c. concrete platform 450 high;
- 5 - electrical wires, switches and fittings are to conform to material standards and safety regulations;

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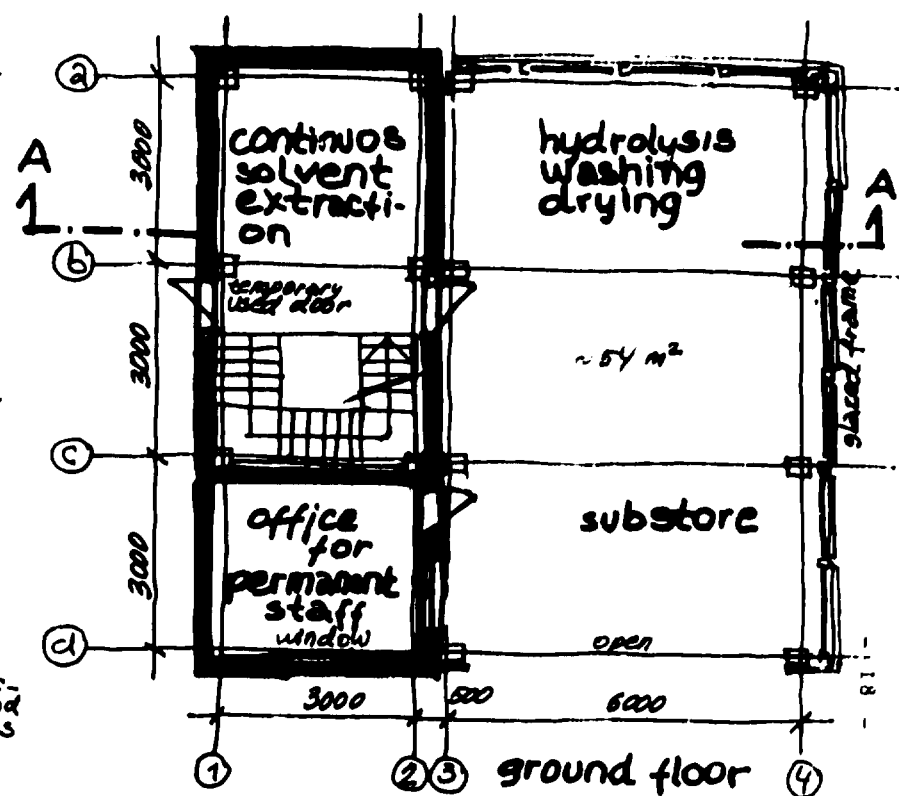
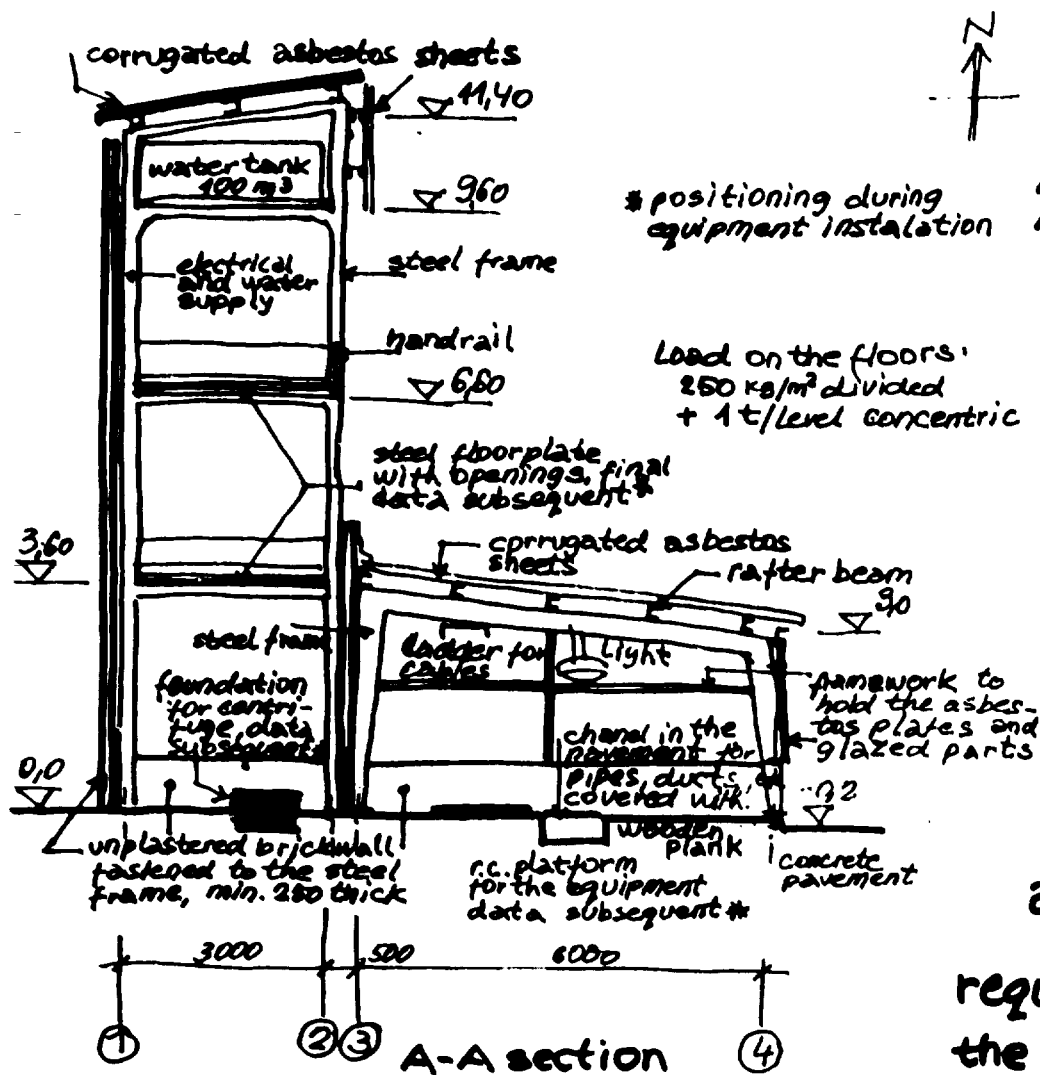
annex 4

existing building  
third floor 1:200

bench-scale  
laboratory

Dr. C.R. Atal  
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J. Silva  
Civil Engineer Consultant



annex 5

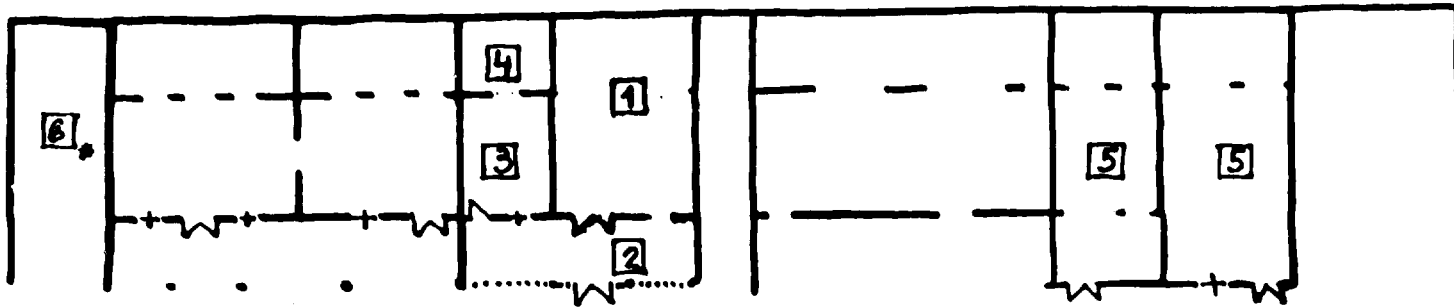
requirements for  
the building '85.oct

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Chief Technical Adviser

I. Széva  
Civil Engineer Consultant

continuous solvent  
extraction and  
hydrolysis unit



\* see annex 1, for correct position

- ① animal cages room and feed store —
  - sloping floor with gutter
  - washable and bactericidal paint on the walls;
- ② corridor and isolation-cages —
  - tiled floor,
  - new enclosure with grill;
- ③ examination-room —
  - sloping floor with gutter
  - washable and bactericidal paint on the walls,
  - laboratory shelves, bench with wash-basin along the wall;
- ④ office —
- ⑤ dried and desintegrated <sup>raw</sup> material storage
- ⑥ Laundry —
  - sloping floor with gutter,
  - automatic wash and drying equipment.

annex 6

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INSTITUTE OF MATERIA MEDICA  
HANOI

existing auxiliary building

modification plan

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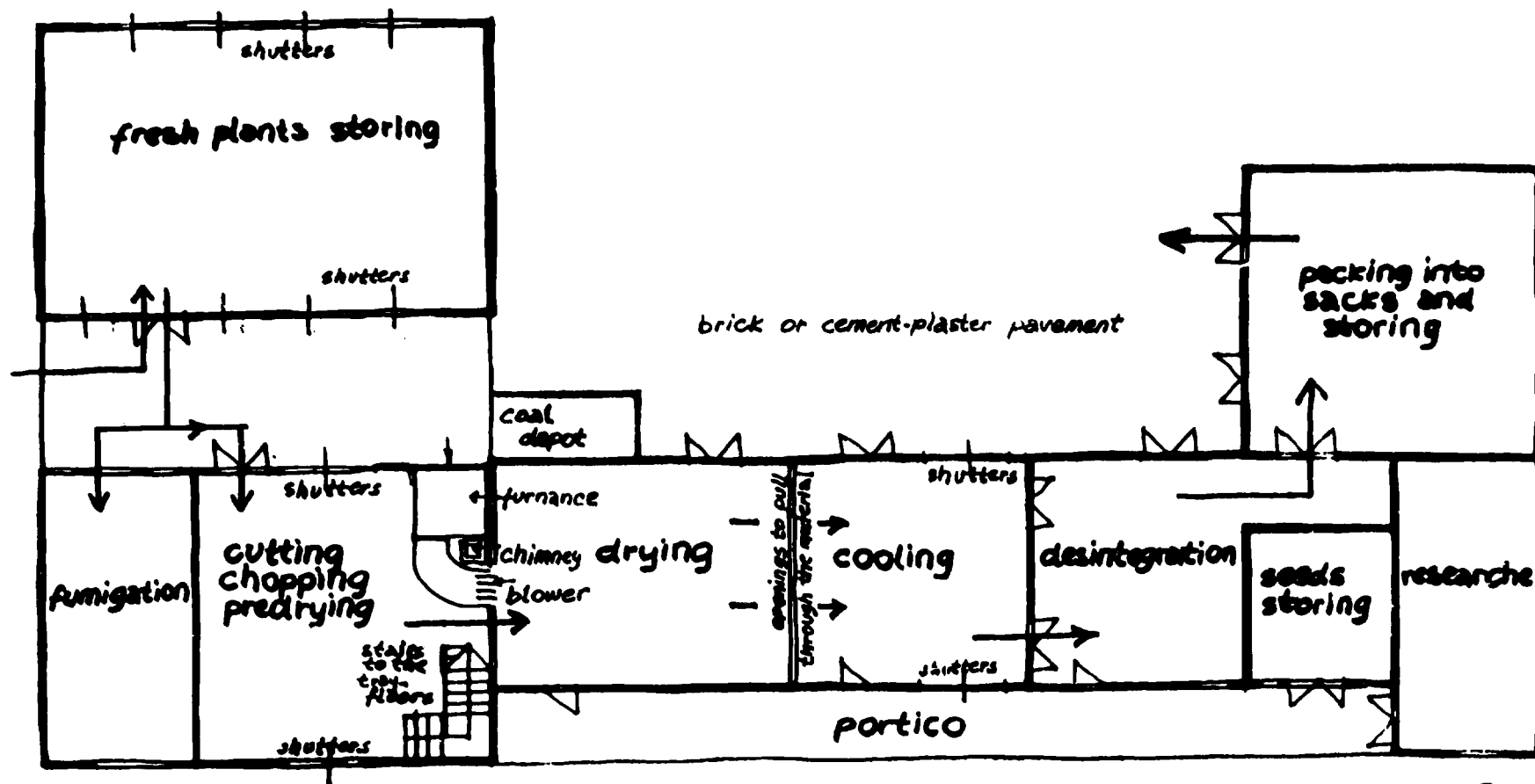
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Chief Technical Adviser

*[Signature]*

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Chief Technical Adviser

*[Signature]*

I. Száva  
Civil Engineer Consultant



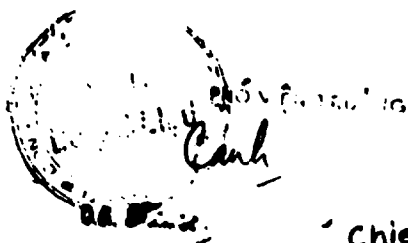
- 20 -

annex 7

requirements '85 oct.

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INSTITUTE OF  
MATERIA MEDICA  
VÁN DIÊN FARM

post harvest  
manipulations  
building



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Civil Engineer Consultant