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13. ABSTRACT (Maximum 200 words)

The goal of the project is to study formalization of regulations and regulatory compliance. Technical objectives involve addressing two verification problems:

- Consistency of regulation / Compliance can be achieved only if the regulation is internally consistent. This verification problem answers the question whether any organization is capable of complying with the regulation.
- Compliance of organizations / This verification problem answers the question whether the operation of an organization complies with the regulation. Formalization and verification questions were studies in the context of a case study that concerns regulation of blood banks by the U.S. Food and Drug Administration in the Code of Federal Regulations that the administration publishes.

Accomplishments
The two major accomplishments of this project are the run-time verification framework for regulatory trace compliance and the application of conformance testing to regulatory compliance of software.

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Enclosure 1

EXTRACTING FORMAL MODELS FROM INFORMAL REQUIREMENTS AND USING THEM FOR VALIDATION

Closeout Report

1 Administrative

ARO grant number: W911NF-05-1-0158.

Project title: EXTRACTING FORMAL MODELS FROM INFORMAL REQUIREMENTS AND USING THEM FOR VALIDATION.

Duration of the grant: 4/15/05 – 4/15/08.

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2 Program Objective

The goal of the project is to study formalization of regulations and regulatory compliance. Technical objectives involve addressing two verification problems:

- Consistency of regulation

  Compliance can be achieved only if the regulation is internally consistent. This verification problem answers the question whether any organization is capable of complying with the regulation.

- Compliance of organizations

  This verification problem answers the question whether the operation of an organization complies with the regulation.

Formalization and verification questions were studies in the context of a case study that concerns regulation of blood banks by the U.S. Food and Drug Administration in the Code of Federal Regulations that the administration publishes.

3 Technical Approach

Our approach was to translate regulation into a collection of deontic logic formulas. The translation involved manual annotation of a substantially large fragment of the regulation, followed by automated parser training. Once the translation was complete, we performed static verification (model checking, conformance testing) on DBSS, a software system for blood bank management. Verification aimed to established whether compliance is ensured by the given software.

We also explored a runtime verification approach. Runtime verification is a technique for monitoring execution traces for compliance. Verification is performed on a log of operations and determines whether performed operations are compliant with the regulation.

4 Accomplishments

The two major accomplishments of this project are the run-time verification framework for regulatory trace compliance and the application of conformance testing to regulatory compliance of software.

4.1 Formalization of regulatory documents

We have developed a translation scheme based on Natural-Language Processing (NLP) techniques. Regulatory documents are translated one sentence at a time, preserving the structure of the regulation. This techniques has two important advantages:

- Structural mapping enhances traceability. Whenever a violation is discovered, our translation allows the verification process to identify the statement in the original regulatory document that was violated.
- Efficiency of the parser is improved, since NLP techniques work best at sentence level.

An important feature of our formalization approach is the explicit representation of exceptions that are omnipresent in regulatory documents. That is, obligations stipulated in a regulatory statement are predicated on exceptions described elsewhere in the document. Exceptions are handled by means of the reference operator, a new modal operator in our logic, along with the deontic operators of permission and obligation. These new modal operators are embedded into linear-time temporal logic (LTL), a commonly used formalism for capturing behavioral and temporal requirements.

Conformance checking is based on existing runtime verification algorithms for LTL. The complication introduced by our formal representation lies in the handling of references. Our algorithm resolves references on the fly by means of annotations that are obtained by a fixed point operator. We have implemented a prototype checker for our logic and applied it to a fragment of the blood bank regulation.

4.2 Conformance testing of the DBSS system

Defense Blood Standard System (DBSS) is the DoD-developed software system for the management of blood bank operations. In our case study, we explored compliance of the DBSS to FDA CFR 610.40 regulation. The case study identified incompleteness in the regulation, where inconclusive test outcomes could be ignored. We have implemented automatic test generator from formal requirements and an automatic test execution engine that executed the generated tests. We have observed several failed tests during the execution of the test suite. Failed tests corresponded to ambiguous requirements specified in the regulation. Incompleteness in the regulation was resolved differently in the implementation and in test generation.

5 Suggestions for the Future

Overall, the project led to a number of successful developments that have reached, or are close to reaching, the technology transfer stage. At the same time, a number of hard open problems in the area of formalization of regulatory documents and conformance checking remain. While academic research will be able to make further progress towards solving these problems, its full potential will be realized only through team projects that bring together academic researchers with domain experts from industry.

EXTRACTING FORMAL MODELS FROM INFORMAL REQUIREMENTS AND USING THEM FOR VALIDATION

ARO W911NF-05-1-0158

Insup Lee, Aravind Joshi
University of Pennsylvania

Goals of the project

- Formalization of regulations and regulatory compliance
- Two verification problems
  - Consistency of regulation
    - Can compliance be achieve? Only if the regulation is internally consistent!
  - Compliance of organizations
    - Does operation of an organization comply with the regulation
- Case study
  - Regulation of blood banks

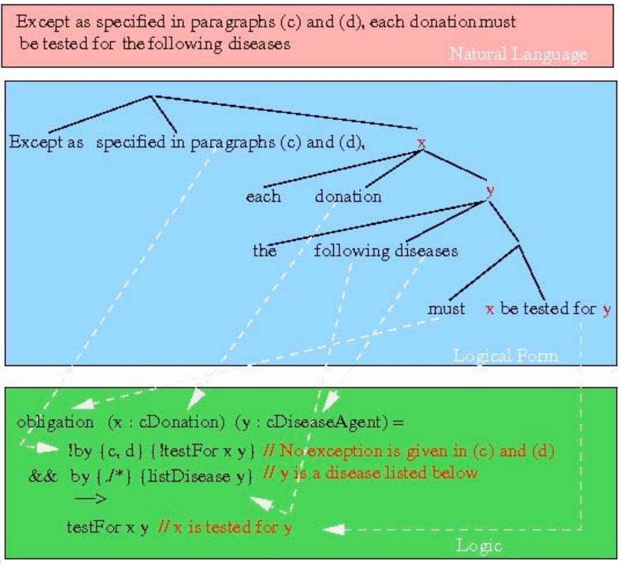
Technical approach

- Translate regulation into a deontic logic
  - Manual annotation
  - Automated parser training
- Static verification (model checking, conformance testing)
  - Given the software for blood bank management, is compliance ensured?
- Runtime verification (monitor trace for compliance)
  - Given a log of operations, is it compliant?

Formalizing regulation

- Approach: regulatory documents are translated one sentence at a time
  - Enhance traceability via structural mapping
  - NLP techniques more efficient at sentence level
- Challenge: cross-references between sentences
  - E.g., actions are predicated on exceptions described elsewhere
- Solution: extend temporal logic with operators for obligation, permission and references

Annotation and translation to logic



Except as specified in paragraphs (c) and (d), each donation must be tested for the following diseases

```
obligation  (x : cDonation)  (y : cDiseaseAgent) =
    !by {c, d} {!testFor x y} // No exception is given in (c) and (d)
  &&  by {./*} {listDisease y} // y is a disease listed below
    —>
    testFor x y  // x is tested for y
```

Runtime checking of compliance

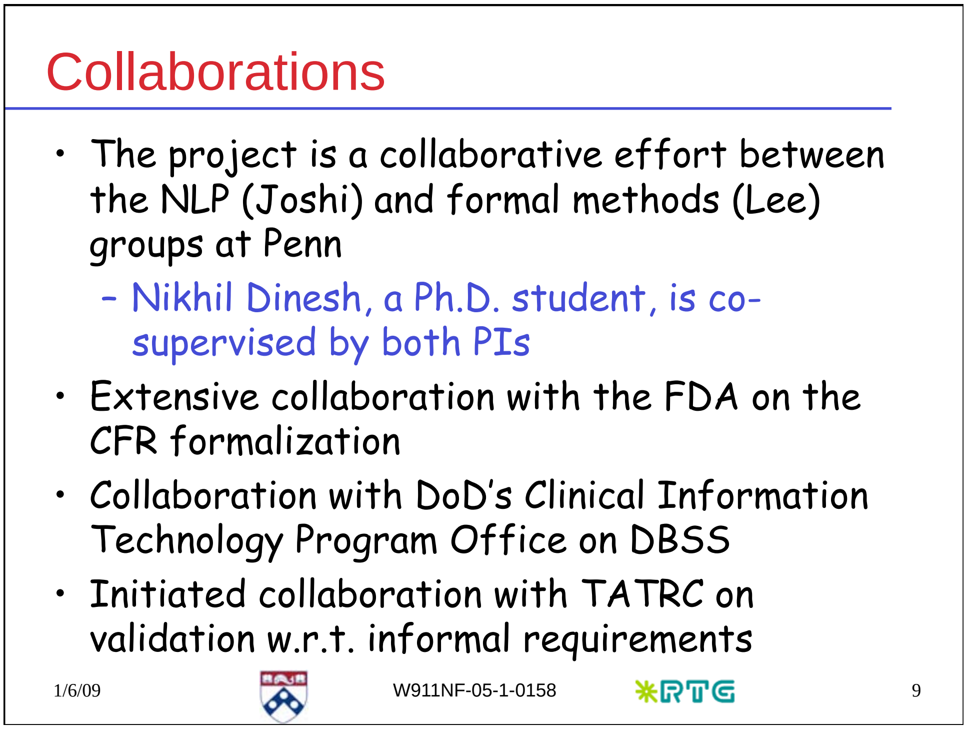
- Reference logic RefL
  - Extends predicate LTL with deontic operators for permission and obligation
  - Introduces operator $by_L(\phi)$, where L is a statement label that captures references
- Checking based on runtime verification algorithms for LTL
  - Algorithm resolves references on the fly by means of annotations
  - Prototype checker implemented

Static verification: case study

- Defense Blood Standard System (DBSS)
  - DoD-developed software
  - Compliance to FDA CFR 610.40
- Identified incompleteness in the regulation
  - Inconclusive test outcomes are ignored
- Technical approach: conformance testing
  - Automatic test generation from formal requirements
  - Automatic test execution engine implemented
  - Failed tests correspond to ambiguous requirements
    - Incompleteness resolved differently in implementation and test generation

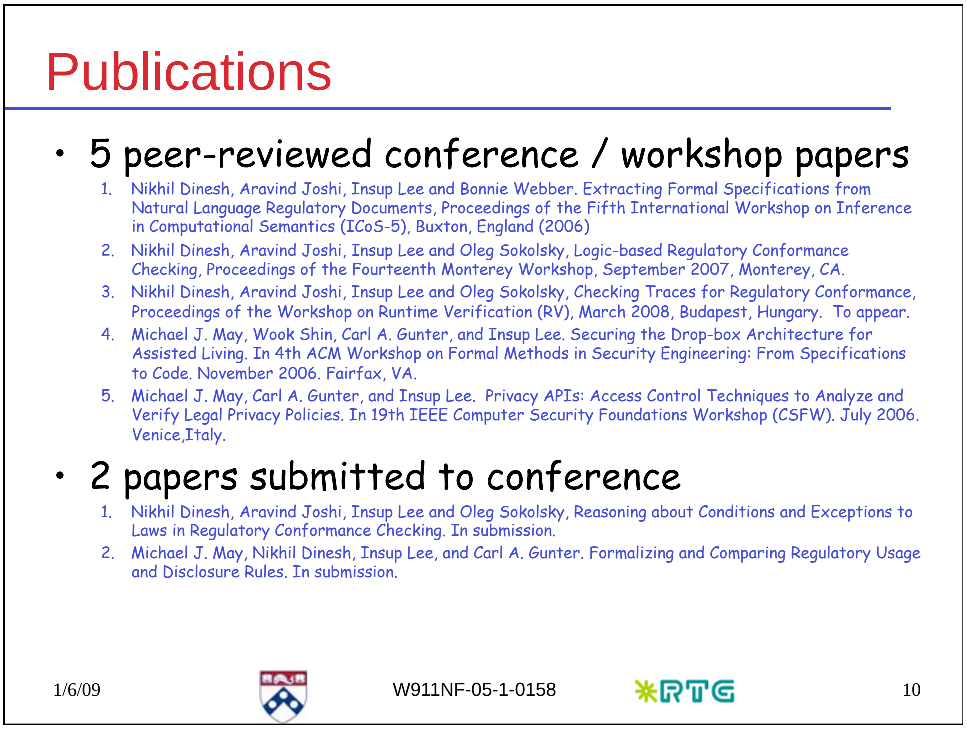
Personnel

- Faculty
  - Aravind Joshi
  - Insup Lee
- Graduate students
  - Nikhil Dinesh
    - NLP, logic, formalization
  - Michael May
    - Policy formalization, logic
  - David Arney
    - Formalization, conformance testing



Collaborations

- The project is a collaborative effort between the NLP (Joshi) and formal methods (Lee) groups at Penn
  - Nikhil Dinesh, a Ph.D. student, is co-supervised by both PIs
- Extensive collaboration with the FDA on the CFR formalization
- Collaboration with DoD's Clinical Information Technology Program Office on DBSS
- Initiated collaboration with TATRC on validation w.r.t. informal requirements



Publications

- 5 peer-reviewed conference / workshop papers
  1. Nikhil Dinesh, Aravind Joshi, Insup Lee and Bonnie Webber. Extracting Formal Specifications from Natural Language Regulatory Documents, Proceedings of the Fifth International Workshop on Inference in Computational Semantics (ICoS-5), Buxton, England (2006)
  2. Nikhil Dinesh, Aravind Joshi, Insup Lee and Oleg Sokolsky, Logic-based Regulatory Conformance Checking, Proceedings of the Fourteenth Monterey Workshop, September 2007, Monterey, CA.
  3. Nikhil Dinesh, Aravind Joshi, Insup Lee and Oleg Sokolsky, Checking Traces for Regulatory Conformance, Proceedings of the Workshop on Runtime Verification (RV), March 2008, Budapest, Hungary. To appear.
  4. Michael J. May, Wook Shin, Carl A. Gunter, and Insup Lee. Securing the Drop-box Architecture for Assisted Living. In 4th ACM Workshop on Formal Methods in Security Engineering: From Specifications to Code. November 2006. Fairfax, VA.
  5. Michael J. May, Carl A. Gunter, and Insup Lee. Privacy APIs: Access Control Techniques to Analyze and Verify Legal Privacy Policies. In 19th IEEE Computer Security Foundations Workshop (CSFW). July 2006. Venice,Italy.
- 2 papers submitted to conference
  1. Nikhil Dinesh, Aravind Joshi, Insup Lee and Oleg Sokolsky, Reasoning about Conditions and Exceptions to Laws in Regulatory Conformance Checking. In submission.
  2. Michael J. May, Nikhil Dinesh, Insup Lee, and Carl A. Gunter. Formalizing and Comparing Regulatory Usage and Disclosure Rules. In submission.